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Quality Assurance in Diagnostic Ultrasound

A Manual for the Clinical User

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
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Quality Assurance in Diagnostic Ultrasound

A Manual for the Clinical User

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WHO Collaborating Center for Training and General Tasks in Radiation Medicine

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Bureau of Radiological Health
Rockville, Maryland 20857

FOREWORD

The Bureau of Radiological Health develops and carries out a national program to control unnecessary human exposure to potentially hazardous ionizing and nonionizing radiations and to ensure the safe, efficacious use of such radiations. The Bureau publishes the results of its work in scientific journals and in its own technical reports.

These reports provide a mechanism for disseminating results of Bureau and contractor projects. They are distributed to Federal, State, and local governments; industry; hospitals; the medical profession; educators; researchers; libraries; professional and trade organizations; the press; and others. The reports are sold by the Government Printing Office and/or the National Technical Information Service.

The Bureau also makes its technical reports available to the World Health Organization. Under a memorandum of agreement between WHO and the Department of Health and Human Services, three WHO Collaborating Centers have been established within the Bureau of Radiological Health, FDA:

WHO Collaborating Center for Standardization of Protection Against Nonionizing Radiations;

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WHO Collaborating Center for Nuclear Medicine.

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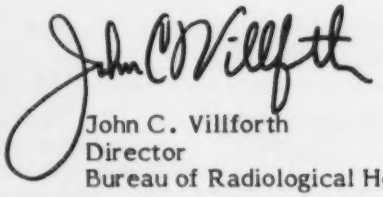

John C. Villforth
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PREFACE

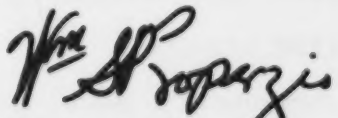
The efficient utilization of radiation in medical procedures is one of the basic goals of the Bureau of Radiological Health. The Division of Training and Medical Applications meets this Bureau goal by several means, including the development and dissemination of quality assurance information and methodology for medical uses of radiation. A Quality Assurance Recommendation for diagnostic radiology facilities has recently been published in the FEDERAL REGISTER. Concurrently, the Division is developing a series of quality assurance instruction manuals. These manuals are part of the "BRH Quality Assurance Publications" series, which provides guidance in the implementation of quality assurance programs for many uses of medical radiation including nuclear medicine, radiation therapy, and diagnostic radiology, as well as diagnostic ultrasound. A listing of subjects and specific titles in this publication series is included on the following page.

The increasing use of ultrasound as a medical tool opens new doors to the field of medical diagnosis. As with any new technology, there exist potential hazards, and care and prudence must be exercised in its use. Thus, the role of quality assurance in this field becomes increasingly important.

This volume, "Quality Assurance in Diagnostic Ultrasound," is intended to be used as a manual for the practitioner and operator of diagnostic ultrasound B-scanning equipment. Also included are techniques and recommendations for taking corrective measures, and discussions are given which may aid in understanding the basic physics of ultrasound applications. The manual also includes information concerning the types of testing equipment which the user can obtain, as well as sources of availability.

This and related manuals will provide the basis for a comprehensive quality assurance program in diagnostic ultrasound. We hope that each facility will evaluate its own needs and adopt as much of this program as appropriate.

We welcome comments on your experience with this manual, as well as suggestions concerning the content, style, and direction of future manuals.



William S. Properzio, Ph.D.
Director
Division of Training and
Medical Applications

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READEX FICHE

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The mention of commercial products, their sources, or their use in connection with material reported in this manual is not to be construed as either an actual or implied endorsement of such products by the American Institute of Ultrasound in Medicine (AIUM), the Department of Health and Human Services (HHS), or the World Health Organization (WHO).

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1

INTRODUCTION

This manual is written for use by clinical personnel (physician or technologist) in the clinical laboratory. Its purpose is to acquaint them with simple basic facts and procedures which will aid in maintaining a high level of performance of ultrasound B-scan equipment.

There is a divergence of opinion on the question of **who** should perform quality assurance in a clinical department. Some feel that it is sufficient for a qualified, knowledgeable physicist or engineer to test the equipment periodically. Others, and this is the author's inclination, feel that quality assurance procedures are best performed by the people who use the equipment daily. The physicist is always available to aid in understanding and interpreting test results and to perform the more exacting acceptance tests. However, with the clinical personnel responsible for the quality assurance of their equipment, quality assurance becomes an ongoing procedure and not just a "once a week" phenomenon.

In his clinical service the author has worked with equipment from several ultrasound manufacturers. The examples given in this manual refer to this specific equipment. This in no way implies that these instruments are better or worse than other instruments in the marketplace.

Reference Section 9.1 contains selected references concerning quality assurance procedures. Readers desiring more information should consult this section.

2

BASIC NEED FOR QUALITY ASSURANCE

2.1 What is Quality Assurance?

In this manual a proper quality assurance program in a diagnostic ultrasound clinical laboratory is defined as all procedures necessary to maintain proper and consistent equipment operation. The end result of a clinical examination is an ultrasound image (sonogram). The patient information contained in this ultrasound image must be maximized and consistent from examination to examination. It is the function of the quality assurance program to keep the diagnostic quality of the ultrasound image at a consistently high level.

2.2 When should Quality Assurance be performed?

Quality assurance procedures must be performed at routine intervals. Since quality assurance in diagnostic ultrasound is a relatively new field, not enough experience has been gained for us to confidently recommend fixed intervals for each of these procedures. At present, based on our experience, it is suggested that the performance tests given in Section 7 be scheduled and performed at least once weekly on each machine.

2.3 Who is involved in Quality Assurance?

The individuals whose effort and/or input are essential for a proper quality assurance program include: the physician, the ultrasound technologist, the equipment service person and, for the more sophisticated tests, a physicist or engineer who is familiar with clinical ultrasound images and the operation of ultrasound equipment.

2.4 How is Quality Assurance performed?

The rest of this document concerns itself with the HOW. It is recommended that the indicated procedures be followed at suggested intervals. It is also essential that the results of tests made on the equipment and all service calls be properly documented.

3

INGREDIENTS OF A QUALITY ASSURANCE PROGRAM

3.1 Proper Equipment Operation

In order to obtain the best possible diagnostic images in a clinical ultrasound examination, the operator must use the ultrasound equipment properly. The section on proper equipment operation discusses the following: operator controls, scanning technique, potential hazards, warmup, hardcopy care and hospital electrical noise. See Section 4 for details.

3.2 Routine Preventive Maintenance

Without a screwdriver or advanced technical knowledge the ultrasound operator can routinely perform certain simple procedures to keep ultrasound equipment running well. The procedures recommended (Section 5) are not hazardous to the operator or machine and can be performed easily. The procedures include hardcopy, air filters, scanning arm stability, integrity of enclosures and worn cables.

3.3 Routine Performance Tests

Routine tests performed at regular fixed intervals ascertain whether or not the machine is performing in a consistent manner. These tests are not quantitative but qualitative. In some tests numerical values of certain machine parameters are obtained. The magnitudes of these numbers are not as important as their consistency each time the test is performed. The author believes that routine performance tests should be designed to be performed by the physician and the ultrasound technologist. See Section 7 for details.

3.4 Acceptance Tests

Acceptance tests are performed by a qualified technical person, to ascertain the safety of the equipment used on patients and to quantitatively measure various parameters of the equipment. The acceptance tests determine whether the equipment is performing at either the level promised by the manufacturer in his advertising or at the level recommended or required by other organizations (AIUM, Government regulatory agencies, etc.). Since these tests are quantitative it is essential that they be performed by a properly trained and experienced person. Acceptance tests for the total system and the individual components are being developed at present. The system variables to be tested are listed in Section 6.

3.5 Documenting Equipment Performance

It is essential that test results be recorded, both at the time of acceptance and in routine performance tests. Records frequently have great value later to provide knowledge of the baseline performance of a particular component in the ultrasound equipment. Eventually this data may also be of great value to the ultrasound equipment manufacturer or the government in recommending future design changes.

3.6 Documenting Equipment Repair

Much unnecessary, unscheduled downtime can be avoided by establishing good communication with the manufacturer's service personnel. Often problems arise from not adequately explaining the difficulty to the service person. On the other hand, sometimes the service person repairs a known problem and also fixes other conditions without telling the users what he has done. Certain adjustments made in this way can affect clinical performance or the results of the next routine performance test. This type of problem can be avoided by keeping a log of equipment repair. A recommended form of the service log is given in Section 7.6. It is also recommended that the relevant performance test be done immediately after a repair call, preferably with the service person present.

3.7 Frequent Consultations with Service People

Modern ultrasound B-scan gray scale equipment is very complex and sophisticated. Your service person is an expert on the ultrasound equipment and should be regarded as a prime source of information regarding proper operating procedures and potential weak points of the equipment. If the service person is called in only when equipment malfunctions, there is a negative interaction with the operators with a resulting negative exchange of important information. On the other hand, if users consult frequently with the service person, asking his advice about equipment procedures, then a good relationship will result and the flow of information is facilitated for the common good.

4

PROPER EQUIPMENT OPERATION

In this section various points on proper equipment operation for specific manufacturer's equipment will be given. Consult your service person for the facts regarding your specific equipment. Some time spent reading the manufacturer's operator's manual will also insure more skill in proper equipment operation.

4.1 Operator Controls

The proper adjustment of knobs or controls on the ultrasound equipment is required for obtaining the optimal clinical images. Particular controls critically affect the image quality.

4.1.1 Contrast Enhance Knob

On most ultrasound equipment a contrast enhance knob can be adjusted to enhance the appearance of low amplitude echoes in the previously obtained ultrasound image. However, on some equipment this control affects the brightness and contrast of **both** the viewing and hardcopy TV's. Thus, changing the setting of this control will also affect a previously set photographic technique. Since the photographic technique was set to optimize the information in the clinical image, any readjustment of the contrast enhance control will certainly change and possibly degrade the ultrasound image. On Picker scanners (80L analog scan converter) and Searle scanners the contrast enhance knob will affect the hardcopy photographic technique. It is recommended that on a B-scanner where the contrast enhance knob does affect hardcopy technique, that this control be left in a standard position (for example, 12 o'clock high).

On certain analog ultrasound scanners, the Unirad for example, there is a post-processing or contrast enhance adjustment which will change the appearance of the low and high amplitude echoes in the image but will **not** affect the photographic technique. The post-processing control on the Unirad scanner changes the assignments of the displayed shades of gray (which echo amplitudes are represented in the image by each shade of gray) but not the shades of gray in the image (viewing or hardcopy TV image).

B-scanners with digital scan converters have a choice of several post-processing schemes. Choosing among these schemes will not affect photographic technique although the images will appear different due to the different gray scale assignments.

If there is a question concerning the low amplitude echoes in a clinical image the best procedure is to rescan the patient.

4.1.2 A-Mode Gain Switch

The A-mode gain switch on Picker scanners affect the amplitude of echoes in the A-mode but not the B-mode display. In the up position the dynamic range (variation between smallest and largest amplitude echoes of the displayed A-mode echo signal) is 12 dB. In the down position of the switch the dynamic range of the displayed A-mode echo signals is over 40 dB.

4.1.3 Logic Lockup

The latest ultrasound equipment contains digital (computer) circuitry. In digital circuits, numbers (not voltages or currents as in analog circuits) are used to represent signal (echo) amplitudes and for control purposes. On rare occasions this equipment will refuse to operate properly or be totally unresponsive to the operator controls. This condition is known as logic lockup.

The cause of logic lockup lies in the fact that digital circuitry functions by storage and transfer of numbers. If a stored or transferred number changes spontaneously (due to heating or component malfunction) then the logical sequence of events necessary for equipment function is interrupted. Since this was an "unplanned" change in a number the equipment cannot, by itself, get out of this logic lockup state.

The way to get out of logic lockup is to totally turn off the equipment — wait one minute and then turn it back on. This procedure takes advantage of the fact that there are digital circuits in the equipment whose sole function is to put the correct initial numbers in key locations when the equipment is turned on. Thus, the turn-on procedure (initialization for purists) will automatically correct a logic lockup state. The only time the initialization procedure will not correct logic lockup is if the

incorrect number is stored in the mass storage (computer tape, disc or floppy discs). Then it will be necessary to replace the mass storage device with a new one.

In summary, if your digital equipment behaves in a non-normal fashion or will not respond to the usual operator controls then just turn it off, wait one minute and turn it back on. If repeated applications of this remedy do not work then call your service person. If logic lockup occurs frequently, then some aspect of the environment (high temperature, static electricity, etc.) is causing spontaneous changes in a susceptible portion of the circuitry.

4.2 Scanning Technique

4.2.1 Scanning Motion

Proper motion of the ultrasound transducer on the patient's skin surface is essential for obtaining optimal clinical images. The operator should be aware that **axial** resolution (the resolution along the central ray of the beam) is superior to **lateral** resolution. Thus, when performing a scan to obtain a measurement or to more clearly visualize certain structures in the body (e.g., vascular lumen) it is essential that the scan for hardcopy be performed with the transducer angulated so that the axial resolution is along the measurement (or visualization) direction.

The scanning technique required for the old bistable displays is different from that required for modern gray scale displays. The older equipment displayed specular echoes from organ boundaries and other large interfaces. The amplitude of these echoes is very dependent on beam orientation, so it was imperative to sector (angle) the transducer constantly during a "pass" across the patient and to perform compound scans in order to properly display ("catch") all of these echoes. Modern gray scale equipment displays low amplitude diffuse echoes from intraorgan structure (small differences in tissue acoustic impedance or structure). These diffuse echoes exhibit less amplitude dependence than specular echoes on beam orientation. Thus, a single scan ("pass") will suffice to image intraorgan echoes. A single "pass" also has the advantage of 1) minimum effect on the image of the lateral resolution (compared to compounding); 2) minimum effect on the image of improper B-mode registration (in a compound scan poor B-mode registration will place the anatomical location of an echo differently for each pass and, thus, cause a blurring of the image); and 3) minimum effect on the image of patient motion (voluntary, peristalsis or respiration). Compound scans (several passes) are useful in (1) avoiding interfering structures (bowel gas), (2) effectively outlining structures of interest, (3) filling in absorption and reflection shadows, and (4) artifact identification.

Proper scanning technique is also important to minimize generation of image artifacts. One example is the acoustic shadow caused by trapped air in the digestive system. The acoustic shadow will always be distal to the transducer along the "line-of-sight" of the ultrasound beam. Different beam angulations cause the acoustic shadow to change position in the image. An important example is scanning of the pancreas. Clinically, a preferred scan plane orientation is one which contains the gallbladder, duodenum and the head of the pancreas. If the duodenum contains an air bubble and the transducer position is lateral aimed medially, then with a linear scan the acoustic shadow of the air in the duodenum can obscure the head of the pancreas. In this case it is better to position the transducer medially and orient the beam laterally to cause the acoustic shadow to fall lateral to the head of the pancreas. Also, the presence of air in the duodenum and the use of compounding techniques can result in a pseudo-mass effect in the head of the pancreas.

4.2.2 Distance Measurements

In the generation of an ultrasound image used to make an internal anatomical patient measurement, it is essential that 1) in acquiring the scan the ultrasound beam be scanned parallel to the measurement direction and 2) that the 1 cm depth marker dots (available on all new ultrasound equipment) be placed on the image along the line of measurement.

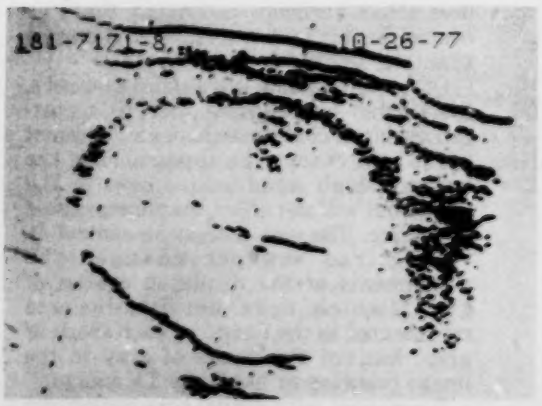

Figure 1. Proper use of the 1 cm depth marker dots in a scan for biparietal measurement.

These two procedures constitute "proper" use of the depth marker dots. Often the depth marker dots will be obscured due to tissue echo information and it is good practice to put another set of parallel depth marker dots adjacent, but in an area where less echoes are present. Fig. 1 demonstrates proper technique in a biparietal measurement. In Fig. 1, the depth marker dots along the line of measurement are obscured by echoes at the proximal fetal skull boundary, so another set of dots was placed laterally.

As explained in Section 6.7, there are certain equipment malfunctions which will lead to B-mode registration errors. In a single pass scan, B-mode registration errors and display nonlinearities cause image size distortion. However, if the depth marker dots are placed "properly" in the image, the distance measurements can be made quite accurately independent of any equipment malfunction.

New B-scanners with digital scan converters usually have a "digital caliper" feature. The accuracy of the digital caliper measurement depends upon proper B-mode registration. If the B-mode registration is in error, then the spatial image data stored in the digital scan converter is distorted and the digital caliper measurement will be in error.

Distance measurements made with proper use of the depth marker dots are independent of B-mode registration errors and display nonlinearities. The depth marker dots are generated by a stable crystal controlled oscillator whose frequency is chosen so that the dots have a time interval identical to the time interval between targets 1 cm apart in a medium whose acoustic velocity is 1540 meters/second. The output of the depth marker dot circuit is sensed by the equipment as input echo information that is along the transducer line-of-sight. Thus, the depth marker dots and the received tissue echoes are distorted similarly by improper B-mode registration. If the tissue measured has an acoustic velocity of 1540 meters/second, then the depth marker dot measurement will be very accurate. Future equipment should allow access (by a buffered connector) to the crystal controlled oscillator circuit so that measurements with a frequency counter can verify its frequency.

When making distance measurements on the image using the 1 cm depth dots as a reference, a measuring device more accurate than a caliper set to a 1 cm distance should be used. For example, in Fig. 1, if calipers are used, then there must be two visual estimates of the millimeter distance made — one at each crossing of the fetal skull with the line of depth marker dots — this can double the total error in the measurement.

A more accurate device is the Gerber 10 inch Variable Scale (Gerber Scientific, Hartford, Conn.). The scale is calibrated to the dot marker distance and then used to measure the image distance to sub-millimeter accuracy. To avoid parallax errors (due to non parallel light rays) always place your eye directly over the point of measurement. For a simple distance measurement this means placing the eye directly over the zero on the scale when positioning the scale and placing your eye over the point of measurement when reading the scale.

On digital equipment it is convenient to use the digital caliper feature to make distance measurements. However, since accuracy in the digital caliper measurement depends upon proper B-mode registration, this parameter should be periodically checked. After verifying the B-mode registration check the digital caliper by projecting 1 cm depth marker dots along the measurement direction and measuring 10 cm along the depth marker dots with the digital calipers. If there is a measured difference, the inaccuracy will most likely be in the digital caliper measurement.

4.2.3 Coupling Medium

An adequate amount of ultrasound coupling gel should be used. If not enough coupling gel is used the amplitude of the received echoes can be reduced. Sometimes this effect goes unnoticed by the operator. To avoid the problem always use a slight excess of coupling material. Also make sure that the shape of the body of the ultrasound transducer does not act as a "snowplow" and push the coupling material aside rather than moving over it.

4.3 Potential Hazards

4.3.1 Changing Transducers

It is common practice to change ultrasound transducers often according to the clinical situation. There is a proper procedure for changing the ultrasound transducer to protect both the operator and equipment. When changing the ultrasound transducer the transmission pulse (the high voltage, short time duration pulse which excites the transducer causing it to vibrate and emit ultrasound waves) should be shut off or re-routed to prevent shock to the operator. On old Picker EDC scanners the through/search

switch should be changed to the "through" position. On newer Picker 80L scanners switch away from the "remote" position on the through-remote-echo switch. On Searle Phosonic and Digisonic scanners the output control should be set to the -24 dB position. In the latter case the proper adjustment of the output knob is not to protect the operator (Searle says the shock hazard is slight), but to protect the ultrasound receiver from unwanted oscillations. Unirad claims that the transmission pulse used in its equipment is so low as to avoid any shock hazard to the operator while changing transducers.

On most ultrasound equipment UHF electrical connectors (male and female) are used to fasten the transducer onto the scanning arm. A difficulty with this particular connector is that one of the electrical connections (the ground) is made via the mechanical fastening assembly (the knurled threaded outer sleeve). If the UHF connectors are not properly fastened mechanically, then they might not be adequately connected electrically. Always make certain the transducer is firmly connected to the scanning arm.

4.3.2 Storing Coupling Medium

When gray scale imaging was first introduced, many operators believed that the viewing TV could be used as a heater for the coupling medium (oil or gel), but this is not recommended practice. There is a chance of a spill. If the coupling medium does get on the ultrasound equipment it can lead to future serious difficulties. The coupling medium should be stored in a separate location close at hand. Various manufacturers offer small heaters for the ultrasound coupling medium. These heaters also provide a secure safe place for the coupling medium away from the equipment. Baby bottle warmers are also useful for keeping the coupling medium warm. Use of a hot plate to heat the coupling medium is dangerous, with a demonstrated potential for starting fires.

4.3.3 Major Cables

On some types of equipment there are main connecting cables between the operator's console and the scanning arm assembly. The weak point in these cables is the connector between the cable and the mainframe or the scanning arm assembly. If by accident, these connectors are kicked or stepped on, serious damage to the machine may result. Try to position the scanner in the room so that these connectors are not readily accessible to mechanical damage.

4.3.4 Electrical Safety

Invasive ultrasound procedures, such as needle biopsy or cyst puncture, or ultrasound examinations of cardiac patients pose an electrical shock hazard to the patient. This is the same type of hazard that patients may face in special procedure rooms, angiographic suites or intensive care units.

The primary danger is electrical shock to the heart muscle or myocardium. This muscle is highly sensitive to electric current. Inside the myocardium are two nodes which generate periodic electric pulses which control the heart muscle contractions. Application of external electrical currents to myocardium can disorganize its normal rhythm and put the heart into fibrillation. A current of 100-300 mA through the whole body (unbroken skin) is sufficient to start fibrillation. A much lower current through a needle or catheter piercing the skin near the heart can produce current densities at the heart sufficient to cause fibrillation (1). Medical authorities consider alternating currents exceeding 10 microamps to be potentially dangerous (2) (3) (4) if the current passes through the heart from a small conductor such as a pacing catheter.

If any ultrasound equipment has high leakage potentials (electrical voltages "leaking" through nonconductive insulation) it might transmit these voltages to the biopsy needle or catheter and introduce microampere currents directly to the heart. Since the threshold of perception for unbroken skin (the sonographer) is in the milliampere range, this leakage current can go unnoticed.

JCAH rules (5) require that all hospital electrical equipment be leakage tested prior to patient use (acceptance tested) and thereafter at routine intervals not to exceed six months. As a prudent user you should adhere to these standards. The danger to the patient can come not only from cracks in the transducer case but from any leakage potential or bad insulation (leakage paths) in the equipment. Have the appropriate technical personnel in your institution perform these tests at the recommended intervals and keep proper records. All transducers should be rechecked at these six-month intervals. The transducer manufacturer will recertify (a leakage test is one component) your transducer for a nominal cost.

Besides leakage testing the prudent ultrasound user will try to maintain the patient electrically isolated from both the equipment and electric ground. Most

commercial coupling gels are highly electrically conductive. If there is access to a non-conductive gel, it should be chosen to maintain patient isolation. This is especially important in any needle puncture procedure or on scans of a patient with an external cardiac catheter or external cardiac pacemaker leads.

On patients with external cardiac pacemakers leads make certain the metal portions of these leads are not exposed. If any metal comes in contact with these leads, the patient may suffer an electrical shock or the leads will be shorted out and the patient will not receive the pacing pulse.

4.3.5 Transducer Sterilization

For biopsy or aspiration procedures the transducer must be sterile. Do not use an autoclave or any other high temperature technique to sterilize a transducer. High temperature, even for a brief period of time, can corrupt the adhesives and plastics used in the fabrication of the transducer. Cold gas sterilization should be used.

4.4 Warmup Procedure

It is important that the ultrasound equipment be properly warmed up in order to obtain consistency in the displayed shades of gray. An important factor for proper gray scale presentation is the thermal stability of the hardcopy TV. The circuit elements (resistors, capacitors, transistors, etc.) in the TV change their operating characteristics as a function of temperature. Thus, when a TV is turned on, its display shades of gray will gradually change until it has "warmed up". It is recommended that this warmup time not be shorter than the manufacturer's recommendation.

In arriving at a proper warmup procedure there are conflicts in requirements of different components of the system. Modern ultrasound B-scanners contain solid state circuitry which is best left on continuously under certain conditions. Transient voltages can be generated by switching equipment on and off. These transient voltages can sometimes damage the more vulnerable solid state components. However, the useful life of the TV phosphor is governed by its "on" time. If one decides to leave the equipment on 24 hours a day, the brightness of the viewing and hardcopy TV's should be turned to minimum to increase TV tube life (by a factor of 3!). However, the useful life of an analog scan converter is measured in hours of usage. Since the analog scan converter is a crucial (and expensive) component in the ultrasound imaging system, its lifetime is of prime importance.

With ultrasound equipment containing analog scan converters, it is recommended that the equipment be turned off at night in order to obtain maximum scan converter lifetime. It is recommended that 7-day timers be used to turn the equipment both off and on. (These may be obtained from lawn care dealers, or some department stores.) The timer should be adjusted to turn the ultrasound equipment on before the first clinical scan. The off time should be adjusted for approximately two hours after the average clinical day. Caution all clinical personnel always to leave the equipment on/off switch in the on position. Set the seven day timers so that the equipment will be off on all non-clinical days (weekends).

With ultrasound equipment containing digital scan converters, it is also recommended that equipment be turned off at night. Digital equipment has heat fatigue problems. It needs an air conditioned environment to aid in cooling the electronic components. If digital equipment is left on at night and the air conditioner turns off for any reason (for safety reasons, the air conditioner won't go back on until manually reset) there is a chance of overheating and major problems occurring. The same recommendation for 7-day timers applies to digital equipment.

4.5 Hardcopy Care

4.5.1 Proper Gray Bar

Photographic hardcopy technique should be set up properly and checked routinely for each hardcopy camera. The image display and hardcopy systems in present ultrasound equipment are the potentially weakest link in the imaging system so they should be checked daily. When testing the photographic technique a gray bar generated by the equipment should be used. There are several possible pitfalls in using the gray bar which the operator should avoid.

The first is that the spatial relationships between the shades of gray are different in a clinical scan and the gray bar. This affects the perception of the gray levels by the viewer. The proper procedure for establishing a good gray bar is to adjust technique until a good clinical scan (or standing liver scan) is obtained and then document this technique with gray bar images. When good tissue equivalent phantoms are available this procedure should be done on the phantom and not on a live subject.

The second is the fading characteristics of the analog scan converter. Image information stored on the analog scan converter slowly degrades in time. Therefore, on analog equipment when

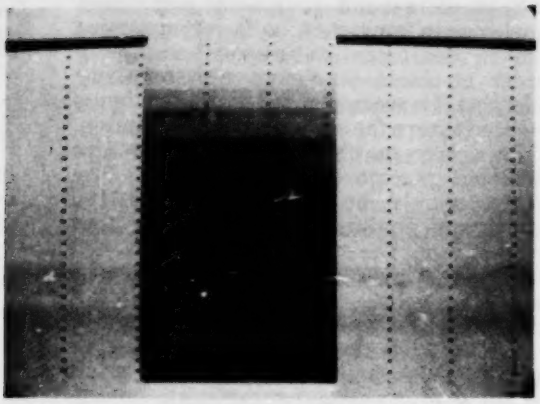

Figure 2. Proper gray bar for Picker EDC Scanners.

generating a gray bar to test the hardcopy it is essential that the gray bar be freshly generated, and the gray bar hardcopy be taken immediately. (This is also proper technique during a clinical exam — take hardcopy immediately!)

The third is that on some older ultrasound scanners, the exact shades of gray presented on the hardcopy TV (and therefore, hardcopy image itself) are dependent on the average video signal in the TV (6). A full gray bar written across the image TV does not contain the same average video level (average shade of gray) as a clinical scan. It is recommended, therefore, that where possible the width of the gray bar may be adjusted to a partial width (one third) gray bar (see Fig. 2) to more closely match the average video signal (average shade of gray) used in this test to that normally encountered in a clinical scan. Or, put another way, the gray bar pattern should have just as much background white as the average clinical scan.

Fourth, the shades of gray are affected by analog scan converter performance (writing speed, focus, etc.). On certain older pieces of equipment the speed of writing the gray bar is controlled by the M-mode sweep control (Picker EDC scanners). Since the exact shades of gray written on an analog scan converter are dependent on the sweep or writing speed it is essential that this adjustment be maintained at a consistent setting. On Picker EDC scanners it is recommended that the M-mode sweep be set at 12 o'clock high before generating an M-mode pattern.

In quality assurance testing using the gray bar on multi-image cameras, the gray bar should be checked on each image format used. When checking Polaroid hardcopy use freshly opened film. If in doubt, open another film pack and recheck.

It is definitely preferable to have a gray bar (presenting all the display shades of gray) on each clinical image. Most new B-scanners have this facility as a standard feature. It is not feasible to "retrofit" a gray bar on existing equipment and certainly not possible on older B-scanners. It is possible, however, for a pseudo-gray bar to be added to old displays for routine monitoring of some features of display performance. A photographic optical density step wedge (Kodak Catalog No. 152-3422, 21 steps), used to calibrate optical densitometers, can be taped on the bottom of the hardcopy TV. The transmitted light from the TV will form a gray bar on the hardcopy. While the shades of gray in the gray bar do not represent the TV shades of gray, this gray bar can be used to monitor the consistency of 1) the TV brightness, 2) the hardcopy camera technique and 3) the processor consistency. The only important variable not checked for consistency with this simple gray bar is the hardcopy TV contrast. Fig. 3 (see next section) illustrates the use of a pseudo-gray bar in demonstrating Polaroid hardcopy deterioration.

4.5.2 Polaroid Images

Although the recent trend is toward multi-image cameras utilizing 8 x 10 x-ray film, many laboratories still use Polaroid images. In certain situations Polaroid images may still be necessary. There are three essential points to remember when using Polaroid film. First, it is a high contrast film so it is essential to maintain proper photographic technique. Also, if the hardcopy TV has a tendency to change its shades of gray as a function of the average video level (average shade of gray in the image) then it is essential to use a "proper gray bar" in setting up the photographic technique.

The second point concerns the effect of humidity on the Polaroid image. The foil wrapper on the Polaroid film pack protects the film against humidity, not light exposure. If the film is exposed to average room humidity for too long a time then the shades of gray in the image will begin to fade. It is strongly recommended that you unwrap the Polaroid film as it is being used during the clinical day.

Fig. 3 shows two Polaroid images of the same standing liver scan (service person). These scans were made during a weekend service call with unwrapped (top) and

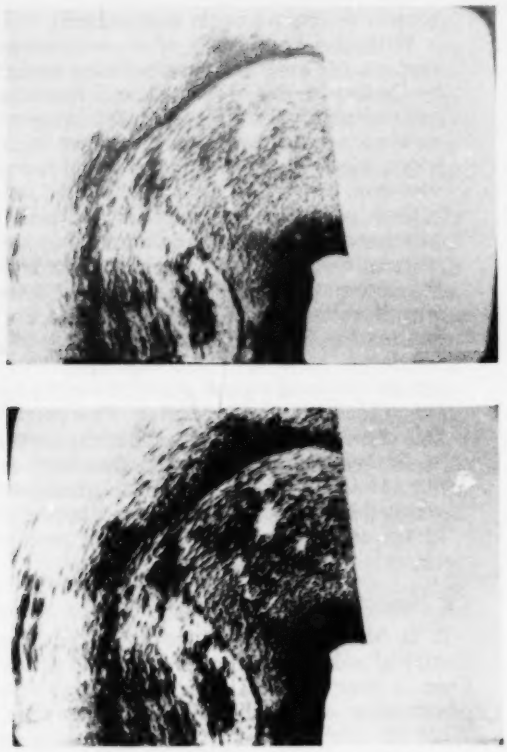

Figure 3. The effect of humidity on Polaroid film. The top film was exposed to room humidity over a weekend, the bottom film was freshly opened. Both are taken from the same TV image.

freshly opened (bottom) Polaroid film. The gray bar is an optical density step wedge (used to calibrate densitometers) taped on the hardcopy TV glass. The washing out of the Polaroid gray scale is well documented in this image.

The third point to remember about Polaroid film is that the development time is indicated on the package and varies with film type and temperature. In general it should not be longer than 3 to 5 minutes. Development of a Polaroid image begins when the film is pulled from the camera (and the chemical pod is broken, releasing the development chemicals). The development is terminated when the Polaroid print is peeled off of the negative. Excessive development times lead to Polaroid images that degrade rapidly in the patient film file.

Polaroid Corporation reminds us that their 107 and 084 films (coating required) have better gray scale imaging properties than their 667 film (coatless). According to Polaroid the 107 and 084 films are also more forgiving to excessive development times.

Polaroid has recently announced a new product, type 611 coatless film. It is advertised to have a dynamic range nearly twice any other Polaroid film (less contrast — more latitude) and allows development times up to 3 minutes without any noticeable change in image quality. When converting to this new film you should adjust the photographic exposure 3 "stops" less than before (it is slower) and set the contrast and brightness on the hardcopy TV monitor for the best visual image (this should make setup easier).

4.5.3 Multi-image 8 x 10 Film Cameras

Multi-image hardcopy cameras are becoming the standard in the clinical laboratory. With the implementation of the multi-image camera it is **essential** that the **automatic film processor** used for development of the 8 x 10 x-ray film be maintained at the correct temperatures and have the correct chemistry. Processor quality control is thus **essential** to the ultrasonographer. If your institution does not have its own processor quality control program already implemented then one **should** be started (7). In the meantime perform your own mini-program. Learn to recognize the problems that are associated with the processors so that the proper maintenance people can be contacted before the problem becomes a major one.

In addition to the processor quality assurance program we suggest checking the ultrasound image gray bar periodically and also at least once each day check the replenisher tank in the processor to make certain there is an adequate supply of replenisher. Nothing degrades the chemistry in the processor faster than the replenisher pump sucking air into the developer! The level of liquid in the replenisher tank must be high enough to prevent this from happening. It is good practice to monitor the temperature of the solutions. Changes in the developer temperature will affect average film density.

Learn from your service person exactly how the multi-image camera functions. On occasion the TV in the multi-image camera will drift in brightness and thus affect the photographic hardcopy. Drifts in TV contrast are much less common but more serious in the sense that the system has to be recalibrated to bring the hardcopy back to the proper density ranges. Learn from your service person how to temporarily override the photographic technique to compensate for TV drifts until repair or recalibration can be made.

Have a technically competent person

acceptance test your multi-image camera and document the tests thoroughly. Time spent at this stage will save time and frustration at a later date. Most multi-image cameras position the images on the 8 x 10 film by mechanically moving the lens (or using a cluster of separate lenses). This results in an optical configuration known as "off-axis" geometry. Off-axis geometry is very susceptible to image distortion and focusing difficulties. Thus, image distortion and focus must be tested initially on the multi-image camera to verify proper design and installation and retested periodically to ascertain that the mechanical operation of the lens movement and position assembly still performs adequately.

The easiest way to check image distortion and focus is to use the alpha numeric (text) capability of your equipment. Generate a full field of the same character (e.g., N's). On each multi-image format available on your camera take images of this pattern (4 on 1, 6 on 1, etc.). Check for image distortion (horizontal and vertical lines in the image are not straight) and for proper focus over all portions of each image (look at sharp edges on the N). [A video test pattern generator is a useful test tool for multi-image cameras (Nuclear Associates, Carle Place, New York, cat. no. 07-471.)]

It should be possible on your new multi-image camera to find the correct brightness and contrast settings for white on black or black on white gray scale presentations. Even if you use only one of these settings exclusively, it is a very good idea to document the necessary brightness and contrast settings for the other should the occasion ever arise. On most multi-image cameras it is possible that the same TV settings can be used for black on white or white on black display modes if the video output signal from the gray scale unit is adjusted by the service person.

The first clinical images obtained on your new multi-image camera might appear to be noisier or contain more photographic artifacts than your previous Polaroid images. These effects might be caused by improper functioning of the new multi-image camera or they might reveal features always present but never seen on Polaroid hardcopy. Check carefully to make certain that the new multi-image hardcopy is not simply making more visible undesirable image features that your equipment has always had. If the new images seem to contain "ghosts," make certain that the proper impedance coaxial cable was used (check this with the service person — 75 ohm cable is standard).

With the installation of a multi-image camera, the gray level presentation should be reviewed. Many ultrasound facilities are switching to a white on black image to minimize transmitted background light when viewing the hardcopy on an x-ray viewbox.

One might consider the additional purchase of simple manual multi-image camera backs to supplement and backup the automatic multi-image camera. These simple units (e.g., NISE Inc., Cerritos, CA) replace the Polaroid backs on the existing hardcopy cameras. The indexing from image to image is performed manually by the ultrasound technologist. The cost of this camera is about 1/6 to 1/8 of the cost of an automatic camera and its purchase, in our opinion, is justified as a backup camera when the more complex automatic multi-image camera is "down" awaiting repair.

4.6 Hospital Electrical Noise

It is not generally appreciated that the electrical noise present on the 115 volt power lines in your hospital affects the maximum penetration observable in a clinical scan. When the clinical situation requires maximum penetration the receiver gain controls are frequently turned to maximum. With the receiver set for maximum gain any electrical noise present, even that on the 115 volt power lines, will be present on the B-mode image as a background low amplitude shade of gray. It is undesirable to have this background present on the image because 1) it does not represent true low-level amplitude echoes coming from inside the patient and 2) the electrical noise will change character from scan to scan and in repeat ultrasound clinical examinations.

It is, therefore, desirable to remove the effects of electrical noise from the ultrasound B-mode and A-mode images. This is accomplished by the manufacturer during the initial installation of the ultrasound equipment. The receiver, when shipped from the factory, is fairly hot (high gain). The service representative will install the equipment and then, using the A-mode presentation with the receiver set at maximum gain, look for electrical noise. Usually there is a good deal of electrical noise present on the 115 volt power line and it will appear on the A-mode as low amplitude echoes (or as it is known in the trade "grass" on the A-mode baseline). The installer will then adjust an internal gain control (not normally accessible by the user) to reduce the effects of this electrical noise. It is important to note that the installer is not cheating the

user. He is not removing any clinical information from the scan because at the highest levels of receiver gain the electrical noise will inevitably override or "swamp" the low amplitude echoes. The installer is merely removing the electrical noise from the image so that it will not confuse interpretation of the scan.

The clinical ultrasound user should consult with appropriate institution technical personnel to reduce electrical noise on the 115 volt power lines to the extent practicable. This may be accomplished by putting the ultrasound laboratory on a separate transformer, by removing heavy duty electrical equipment from the same power line (such as elevators or centrifuges) or by removing conduit grounds. When the electrical noise has been reduced, ask your service person to readjust the internal gain control to correspond to the new lower electrical noise level.

It is recommended that the internal gain be set so that a slight amount of electrical noise appears on the A-mode baseline at maximum gain. While this may seem bothersome at first the visible noise is a check that the internal gain control has not been set at too low a value. Also the ability to view the electrical noise may come in handy when there is a question concerning changing noise levels or receiver gain.

If electrical noise on the 115 volt power lines can be reduced by a factor of 2 then the receiver gain can be increased by 6 dB without introducing electrical noise on the B-mode images. 6 dB of additional gain means at least an additional 1.33 cm penetration at 2.25 MHz center frequency or 0.86 cm penetration at 3.5 MHz center frequency. Every little bit helps.

An alternative approach is to specify better d.c. regulation and/or sufficient filtering in the ultrasound equipment. This increases the cost but may be cheaper to the user in the long run. An inexpensive partial solution is the purchase of a SOLAR transformer. Be sure to purchase the SOLAR transformer whose power rating is closest to the power rating of the ultrasound equipment.

5

ROUTINE PREVENTIVE MAINTENANCE

The procedures discussed in this section are simple and can be performed readily by the clinical ultrasound personnel.

5.1 Hardcopy

5.1.1 Polaroid Images

There are two areas of preventive maintenance associated with Polaroid images. The first is routine cleaning of the Polaroid camera back. The rollers inside the Polaroid camera become contaminated with development chemicals. It is necessary at least **every other day**, and preferably once a day, to clean these rollers. Water may be used but an alcohol wipet is recommended. Also remove any dust from the back of the camera that might contaminate the film or the back of the lens.

The second area of preventive maintenance is proper handling of the film. Polaroid film should not be removed from its foil wrapper until you are ready to take images. Without the foil wrapper the film will absorb moisture from the air and the displayed shades of gray will become washed out. Polaroid images should not be developed for longer than 3 to 5 minutes (See Section 4.5.2 for details).

5.1.2 Multi-Image Cameras

The new multi-image cameras should be checked daily for dust. Some of the cameras have openings on top for the film cassette which remain open when the film cassette is not in place and thus the inside of the camera tends to collect dust. It is recommended that a cassette be kept in these cameras at all times to minimize dust buildup. When checking for dust look carefully at the face of the TV monitor. In most multi-image cameras the TV monitor is on the bottom of the unit facing up and, thus, the TV face is a natural collecting place for dust (and future image artifacts produced by the dust). Also remove, clean and reinstall the air filter (See next section for details).

Proper quality control of the automatic film processor is also important in maintaining consistent quality of the multi-image pictures. If a quality control program for automatic processors is not in operation at your institution then one should be started not only for the CT/Ultrasound images but also for general radiography. (See Section 4.5.3.)

5.2 Air Filters

As mentioned previously, the solid state circuitry present in the equipment is very vulnerable to high temperatures. A supply of circulating cool air is needed to prevent excessively high temperatures. This is usually accomplished by mounting a fan on the back of the unit with the fan forcing hot air out and drawing cooler air in. Located at several strategic spots on the equipment are input openings for outside air. Each opening is covered by an air filter to trap dust. It is important and necessary to routinely clean these air filters to maintain an adequate air flow.

If the air filters are not clean, they lose their efficiency in passing air and the action of the fan will then suck the cooling air through any hole in the shell of the equipment, usually the small holes from which the control knobs protrude. Dust trapped on oil spills or oily knobs can then be sucked into the machine, deposit on critical circuit elements, and lead to their premature failure.

The air filters should be removed periodically and cleaned. The method varies, including cleaning by hand, compressed air, or a stream of water from a faucet. Consult with your service person for the recommended procedure for your particular equipment. After filters on your equipment are cleaned or replaced, make a visual check for dust in the openings of the shell where the control knobs protrude.

On Searle scanners there is an air filter in the front of the bottom drawer of the equipment. This air filter is not easy to remove. It should be removed and cleaned by the Searle service person on each service visit. Always check to make sure that this cleaning operation was performed.

5.3 Scanning Arm Stability

The articulated scanning arm on your B-scanner performs two vital functions. The first is to track the position and angulation of the ultrasound transducer beam in the scan plane. The second is to restrict the ultrasound beam to the scan plane. If there is excessive

mechanical play or movement in the scanning arm, the ultrasound beam will either not be tracked correctly or echoes from adjacent slices will be present in the scan plane image. There is disagreement among users as to how "stiff" the ultrasound arm should be (i.e., how rigid the arm should be to prevent scanning outside of the indicated scan plane). Whatever your preference, it is possible for the arm to become too loose and thus introduce improper echoes in the image. Poor arm handling techniques by the user is a prime source of scan arm difficulties.

Scanning arm locks and magnetic latches should also be checked. The locks on the scanning arm should be used as locks and not as brakes. A lock is a mechanical device to maintain a fixed position of a mechanical assembly. A brake is a device used to slow down the mechanical motion between two parts in an assembly. If locks are used as brakes there will be excessive mechanical wear and after a while they will not function properly. The recommended procedure is to stop the mechanical motion of the arm first and then set the lock. Do not use the lock as a brake!

5.4 Integrity of Enclosures

Doors and other openings on the equipment should be closed during the routine operation of the equipment. On some equipment if any doors or drawers are left open then the cooling fan will efficiently suck in air and dust through this opening and onto the electronics. This is detrimental to consistent long term operation of the equipment.

5.5 Worn or Frayed Cables

With daily use the electrical coaxial cables which connect the various components of the system suffer mechanical stress. If the electrical connections inside coaxial cables break or become loose, the equipment will not function properly. The most common failure is an internal break in the center conductor of the cable. This is frustrating to the user because the machine "works" or "doesn't work" intermittently. If your equipment begins to function in an intermittent fashion, call your service person to check your cables for breaks (perform continuity checks with an ohm meter). The most vulnerable portion of a cable is the joint between the cable and the connector.

6

SYSTEM PERFORMANCE AND TESTING

6.1 Introduction

The tests presently recommended for checking equipment performance are given in Section 7. They make use of the generally accepted test object in the field — the AIUM 100mm Test Object. Many investigators are developing new procedures for routine performance tests and acceptance tests which will become the accepted procedures in the future. The development of tissue equivalent phantoms is an exciting new field.

In this section the components of the B-scan ultrasound imaging system are discussed individually. General information and suggestions are given which should educate the user concerning equipment operation and help maintain consistent, high quality ultrasound images. The parameters are identified which should be measured in routine performance tests and acceptance tests. References to current work are given for those interested.

6.2 Transducer

6.2.1 Frequency

The frequency of the ultrasound transducer is a vital parameter. The higher the frequency, the better the resolution but the less the penetration into the patient. The transducer when supplied by the manufacturer has a nominal center frequency indicated on its case. The actual center frequency is usually 10% of the indicated nominal center frequency. At present there is no easy way for clinical personnel to verify the transducer frequency. New frequency test objects and procedures are being developed (8) (9).

Recent research by the author (10) indicates that the actual operational frequency of a transducer depends crucially on the exact commercial equipment to which it is attached and the exact operator knob settings on the equipment (for certain manufacturer's equipment). Thus, it is necessary for the clinical personnel to have a quick and easily interpretable measure of transducer frequency in the clinical laboratory.

Transmission frequency data was obtained with a frequency independent hydrophone and displayed on a spectrum analyzer. Fig. 4 shows the results obtained for four nominal 2.25 MHz transducers as a function of the output knob setting (which varies the load resistance damping the transducer) on a Picker 80L analog scan converter unit. The peak frequency in the spectrum is plotted because this, at present, is the measurement performed by the transducer manufacturer. It can be seen that the frequency spectrum of the transducers can vary considerably in clinical use. Repeat measurements on a Picker 80L with a digital scan converter demonstrated a nearly constant frequency with output settings. The output circuit has obviously been improved on this newer equipment.

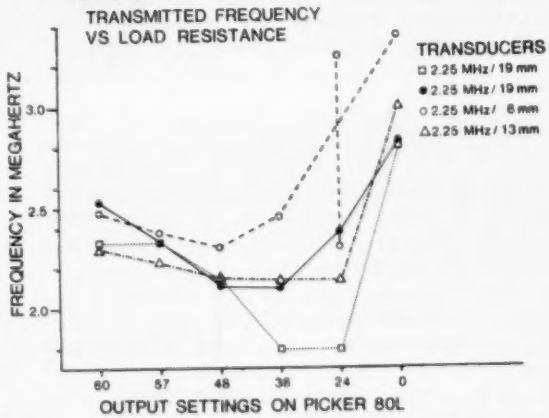

Figure 4. Variation of transducer peak frequency with output control on Picker 80 L, analog scan converter. The vertical line connecting similar data points indicates a broad peak in the frequency spectrum.

Fig. 5 shows the results obtained for four nominal 3.5 MHz transducers when they were connected to different clinical equipment. The 25 ohm load resistance is a standard damping resistance. These results demonstrate the variability in transducer performance even when used with different equipment from the same manufacturer.

Fig. 6 shows the results obtained from a nominal 2.25 MHz transducer with different lengths of coaxial cable connecting it to the equipment main frame. This data is interpreted as the

effect of the changing cable impedance (capacitance) on the transducer's electrical damping. The typical length for B-scan transducer cable is 28 feet. This data is important because it indicates that the transducer manufacturer should check the frequency of transducers not only with the electrical impedance equivalent circuit of the specific B-scanner for which the transducer is intended but also with a 28 foot cable.

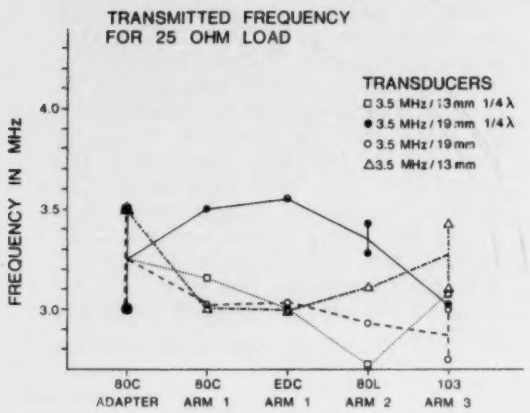

Figure 5. Variation of transducer peak frequency on different clinical equipment from the same manufacturer (Picker). The vertical line connecting similar data points indicates a broad peak in the frequency spectrum. The 80 C adapter is a five foot cable used for converting B-scan transducers to cardiac use.

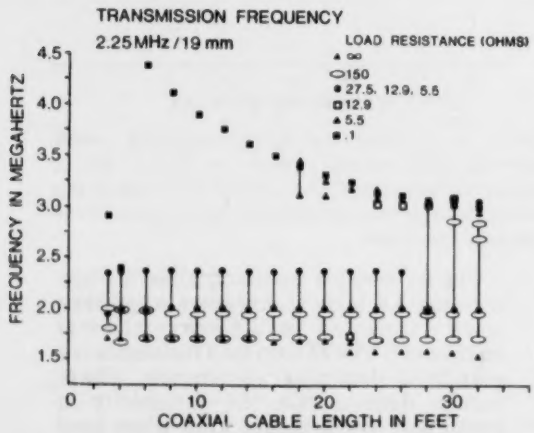

Figure 6. Variation of transducer peak frequency with cable length on a Picker 102 B-scanner. The vertical lines connecting similar data points indicates a broad peak in the frequency spectrum. A cable length of 28 feet is typical for a B-scanner.

6.2.2 Bandwidth (Axial Resolution)

The bandwidth of the ultrasound transducer is defined as the range of frequencies contained in the ultrasound pulse. Basic physics tell us that a short pulse (for good axial resolution) contains a large range of frequencies (large bandwidth). The pulse length (in time or space) and the bandwidth are inversely proportional — as the bandwidth decreases, the pulse length increases. Fig. 7 shows targets to be resolved axially, along the axis of the transducer beam pattern (along the transducer line-of-sight). The axial resolution (bandwidth) of the ultrasound pulse should be measured initially as an acceptance test of the transducer and routinely as a test of continued integrity of the internal structure of the transducer.

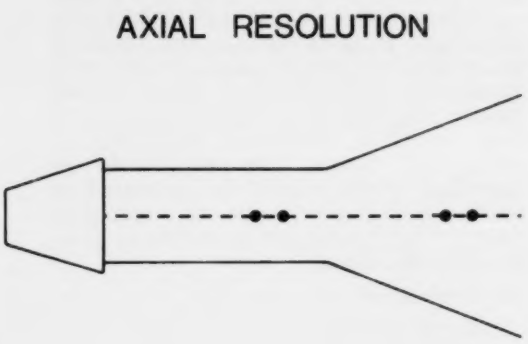

Figure 7. Axial Resolution is the ability of the equipment (transducer) to identify two closely spaced reflectors along the beam axis (line-of-sight).

The axial resolution of the transducer is an important parameter for two reasons. The first reason is that in single pass scans the axial resolution determines the highest resolution capabilities in the image (along the transducer line-of-sight).

The second reason is that the axial resolution is an indicator of the integrity of the transducer. If the transducer suffers mechanical shock then the most likely break will be either a crack in the piezoelectric crystal or a separation (delamination) of the piezoelectric crystal from the backing or damping material. In the latter case the axial resolution of the transducer will decrease greatly (by factors of two or more). Thus a routine check of the axial resolution of the transducer is a quick and easy method of determining the integrity of the transducer. See Section 7.4.5 for details.

6.2.3 Intensity

Due to the finite possibility of biological risk being associated with the clinical use of diagnostic levels of ultrasound radiation, the intensity in the ultrasound beam is an important parameter to be measured. The intensity is specified in the units milliwatts/cm^2. The measurement of acoustic intensity is an important topic that has been discussed at length in many journal publications (11) (12). For our purposes in this Quality Assurance Manual, we simply note that at present there is no simple, proven, commercially available device for reliably measuring the output intensity of a transducer.

6.2.4 Beam Pattern (Lateral Resolution)

The beam pattern of the ultrasound transducer is a crucial parameter. The limiting resolution in an ultrasound image is caused by the beam width. Using different focusing principles (curved crystals or acoustic lenses), manufacturers have designed transducers to have a narrow beam width at a certain distance from the transducer face. The distance (depth in patient) from the transducer face to the minimum beam width (best lateral resolution) is called the focal length. The focal zone (range) is the range of depth around the focal length for which the beam is sufficiently narrow. Fig. 8 demonstrates the definitions of focal length and focal zone.

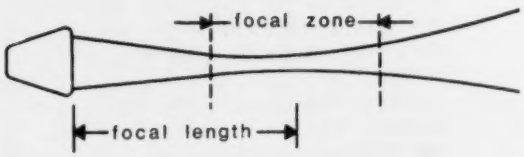

Figure 8. The focal length and focal zone of a focused ultrasound transducer.

There are many definitions of focal zone in use at present, for example: 1) the distance along the beam central ray between the two points whose reflected echoes (for a sphere or rod) are 6 dB lower than the maximum echo (at the focal length), 2) the distance along the beam central ray where the beam width is less than twice the minimum beam width, or 3) the distance along the beam central ray where the beam width is less than $\sqrt{2}$ times the minimum beam width.

The lateral resolution is the ability of the transducer beam pattern to resolve two reflectors separated lateral (perpendicular) to the axis of the beam (Fig. 9). In general the lateral resolution depends crucially on the beam width and is different in the near or far fields of an unfocused transducer. Narrow beams give better lateral resolution.

LATERAL RESOLUTION

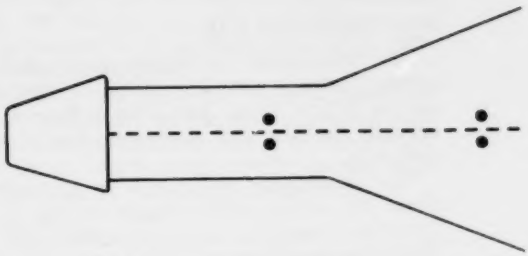

Figure 9. The lateral resolution is the ability of the equipment (transducer) to resolve two reflectors separated lateral to the beam axis (line-of-sight).

If the transducer beam pattern is strongly focused then the focal zone will be short and the lateral resolution will be good for only a limited depth in the patient. This type of transducer should be used for examinations where the target distance is fairly standard — cardiac scans are a good example. For general abdominal B-scans a transducer with a weak focus (collimated beam) is more useful. This transducer will have a long focal zone and a more uniform lateral resolution with depth. Fig. 10 illustrates the difference between weak and strong focusing.

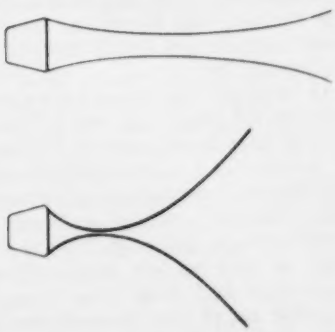

Figure 10. The beam patterns of a weakly focused (collimated) transducer on top and strongly focused transducer on bottom.

The beam pattern should be measured as a transducer acceptance test and also to aid the user in transducer selection for various clinical exams. Various test objects have been developed to measure the transducer beam pattern (13) (14) (15). A rough indication of the beam pattern can be obtained with the AIUM 100mm Test Object (see Section 7.4.5). Recent research (16) indicates that the beam pattern measured in water will be better (narrower) than the beam pattern in a patient.

6.2.5 Transducer Case

The "transducer" we hold in our hands in contact B-scans contains, inside its case, a piezoelectric disc, backing material, acoustic baffles and electrical damping elements.

The transducer is pulsed up to 1000 times per second with voltages as high as 900 volts (depending on the manufacturer). While the energy contained in each pulse is not great, there is an electrical shock hazard to the patient or operator. The transducer is double insulated. The electrical circuit is designed (for contact B-scan transducers) so that the bottom disc surface which could possibly (by accidental rupture of the case) come in contact with the patient is at ground (earth) potential. The transducer case is made of non-conductive materials to prevent electrical connection between the patient and voltages inside the case. If the transducer case develops any openings, cracks or other voids, then the transducer is not suitable for patient use and should be removed from clinical service immediately and replaced as soon as possible.

A visual check of the integrity of the transducer case is an important "acceptance" test for new transducers and a necessary routine check for all those in clinical service. Transducer manufacturers will recheck the electrical insulation of their transducers for a modest fee (see Section 6.2.7).

All medical transducers are electrically shielded (rf shielding) inside the case to prevent pickup of stray electrical signals (it can act like a miniature radio antenna). New digital B-scanners require transducers with "heavier" shielding because their amplifiers are more sensitive to electrical noise as well as low level echoes. It is recommended that you purchase a complete set of new transducers for your new digital equipment. This is not duplication since the older transducers may give poorer performance (and thus, poorer images) on the new equipment.

Another aspect of the transducer case is the degree of mechanical alignment (or misalignment) between the electrical connector and the acoustic axis (central ray) of the beam pattern. For proper B-mode registration the acoustic axis of the beam should be identical with the direction (axis) of the third arm (of the B-scanner articulated arm) on which the transducer is mounted. When the transducer is mounted tightly on the arm the axis of the electrical connector will be parallel to the third arm axis. If the transducer connector/acoustic axis alignment is good then the B-mode registration will not be impaired.

If there is a connector/acoustic axis misalignment then the B-mode registration will depend on exactly how the transducer is mounted on the third arm. When the acoustic axis (different from third arm axis) is in the scan plane the B-mode registration will be most affected. When the acoustic axis is rotated 90° from this orientation (by rotating the transducer case 90°) there will be minimum effect on B-mode registration (but a scan plane slightly tilted from the one intended). One test for connector/acoustic axis misalignment is repeat scans of the AIUM 100mm Test Object (see Section 7.4.4) with the transducer case rotated in two 45° increments. Connector/acoustic axis alignment is measured directly with a new beam pattern test object (14).

Recent reports claim excessive mechanical wear of the electrical connector on the third arm. Specifically, the central post inside this connector is reduced in diameter until proper electric mechanical contact is compromised. The cause of the wear is the rubbing that results when the transducer case is screwed onto the third arm. To prevent excessive wear the recommended way to mount the transducer on the third arm is to push the transducer onto it while rotating the knurled outer sleeve of the connector on the third arm.

6.2.6 Purchase of Transducers

There are two sources for purchasing transducers, directly from the transducer manufacturer or through your B-scanner manufacturer with usually no cost difference between these two. It is recommended that all transducer purchases be made through your B-scan manufacturer. There are four reasons for this recommendation.

First, both the transducer manufacturer and the B-scan manufacturer put the transducers through stringent tests (for

details see Section 6.2.7). When you purchase from the latter you have a product that has been tested twice.

Second, the performance of a transducer depends critically on its electrical environment (see Figs. 4 and 5, Section 6.2.1). The matching between the electrical impedance of the transducer and the electrical impedance of the B-scanner's "front end" (pulser, receiver, etc.) to which it is connected is the vital parameter. Each commercial B-scanner has a different impedance requirement for the transducer. A transducer which performs superbly on one manufacturer's B-scanner might give unacceptable results on another. Thus, it is essential that the transducer be performance tested on the exact B-scanner with which it will be used. While the transducer manufacturer should have an electrical "mock-up" of most B-scanner "front ends," the B-scan manufacturer will probably test the transducer on a machine exactly equivalent to your equipment including all the latest electrical circuit modifications.

Third, the B-scan manufacturer has a group of sales representatives who can give face to face service, a service that the transducer manufacturers cannot provide.

Fourth, the fabrication of transducers is an art. In our competitive, fast growing field with demands on increased performance the transducer manufacturers are constantly striving to improve their product. The B-scan manufacturers buy transducers from many manufacturers. At any specific time for a particular B-scanner one transducer performs better than another vendor's product. This is a constantly changing situation and is a healthy aspect of the growth of ultrasound as an imaging modality. Naturally, the B-scan manufacturer has more knowledge of the specific time dependent variations between transducers and will give the clinical user the best available transducer for his equipment.

6.2.7 Certification

The tests performed on transducers by manufacturers prior to clinical use include: sensitivity check, real-time waveform (check of damping), beam profile, frequency spectrum (center frequency and frequency content), connector/sound beam alignment, electrical insulation safety check and a check of the rf shielding. The test results are supplied by the transducer manufacturer and should be on file with the B-scan manufacturer who sold the transducer. Most of these test results will be supplied to the purchaser free of cost if the request is made at the time of purchase. Beam profile data will usually be provided at a nominal extra cost if specified at the time of purchase.

Always request this information when buying a transducer. It will be valuable if there is a later question as to the performance of the transducer (consistency check). This information **should never** be used in lieu of acceptance tests since the performance of a transducer depends vitally on the equipment to which it is connected. The transducer's performance on the test set up will probably not be equivalent to its performance with your clinical equipment.

For a nominal fee some transducer manufacturers will do recertification tests on your transducers. The most important of these tests from the safety standpoint is the check of the electrical insulation.

6.3 Receiver

The receiver in the ultrasound equipment is defined here as the combination of the preamplifier, logarithmic amplifier (with overall gain and swept gain adjustments), a rectification circuit and a demodulation (smoothing) circuit.

6.3.1 Sensitivity

The overall sensitivity of the receiver (amplifier) is important. The sensitivity or maximum attainable gain should be specified in the dB notation. The dB sensitivity of the receiver along with the sensitivity, frequency, and bandwidth of the operating transducer determines the maximum penetration in a given clinical examination. It is important that the dB sensitivity be as high as possible and constant with time over the long term. New B-scanners are using more powerful amplifiers and may require the use of heavier rf shielded transducers to minimize low level electrical pickup.

6.3.2 Dynamic Range

The dynamic range of the receiver (amplifier) is also an important parameter. The dynamic range is defined as the ratio, in the dB notation, between the largest echo amplitude received from the patient (which passes through the receiver without limiting) and smallest echo detectable received from the patient (which is discernable above noise in the receiver output). It is known that the echoes received from the patient by the transducer have at least 100 and probably 120 dB dynamic range.

Another crucial parameter in evaluating

the receiver is the dynamic range, expressed in dB, for a given depth in the patient. At present it is felt that the useful echo information at a given depth covers the dynamic range of roughly 30-40 dB (the dynamic range of tissue reflection coefficients at that depth). Thus, the receiver should have commensurate dynamic range at a given depth in the patient (i.e., at a given fixed value of the gain voltage).

The maximum dynamic range at a given depth which may be usefully utilized in a clinical examination is limited by the transducer beam pattern. If the receiver has too large a dynamic range at a given depth for a certain transducer beam pattern, then artifactual information may appear in the image. For example, the side lobes from a perfect plane piston continuous wave radiator (unfocused circular transducer) have a maximum theoretical amplitude of 17.5 dB down from the main lobe. If the ultrasound receiver has too large a dynamic range at a given depth (and/or the transducer has excessively strong side lobes) then side lobe information in certain instances (cysts) will be larger in amplitude than echoes from the main lobe and erroneously placed in the image along the direction of the transducer central ray (inside the cyst).

6.3.3 Noise

A measurement of the noise in the receiver is also an important parameter. Usually the noise level present in a receiver is determined not by electronic design considerations but by the electrical noise present in the 115 volt power lines in a clinical laboratory. (See Section 4.6.)

6.4 Analog Scan Converter

Present ultrasound B-scanners use a scan converter (memory) to store the image data prior to display. The definition of a scan converter is a device which stores information acquired with one given scan format (in our case, random xy scan format) and outputs this information in a different format (in our case, TV format with 525 horizontal lines, 30 frames per second, etc.).

The analog version of the scan converter has several serious limitations: expense, limited life, volatile storage of information (the information stored degrades with time), a limited dynamic range of stored information, blooming of the echo information, difficulty of focusing and drifts in the focusing properties and brightness settings. With one manufacturer's analog scan converter, seven separate focusing adjustments are necessary. Each of the seven separate focusing adjustments affects the other six. Therefore, in focusing the scan converter the repair person must perform the seven focusing adjustments in sequence over and over again until adequate performance of the scan converter is attained. This is a time-consuming, hit or miss procedure. It is essential that the proper focus of the scan converter be verified over the used portion of the scan converter image. The suggested test for analog scan converter focus is given in Section 7.4.1.

Fig. 11 shows the basic design of an analog scan converter. Electrons produced by an electron gun are accelerated toward the target by a high dc potential. Electrostatic (shown here) or magnetic deflection is used to aim the electron beam onto any spot on the target. The target is a surface on which a square array of tiny capacitors has been formed using modern planar technology.

The array of capacitors is used to represent the patient scan plane. The charge stored on each capacitor represents the echo amplitude received from that specific spot in the patient. The echo amplitude information is stored in the analog scan converter by using the electron beam to "write" onto the target. In "writing" the path of target spot (the point of impact of the electron beam on the target) follows the trajectory of the ultrasound pulse in the patient scan plane. In "writing" the analog scan converter operates in an "equilibrium writing" mode where a capacitor is only charged if the newly acquired echo amplitude is larger than the previously stored echo amplitude. Thus, the scan converter stores the "peak" echo amplitude measured from each anatomical point.

In "reading" the electron beam is used to measure the charge stored on each capacitor. Since the scan converter is used as the memory for a TV display, the target spot scans the target in TV format (525 lines per image, 30 images per second) as shown in Fig. 11. The reason for tilting the "streets" and "avenues" of the capacitor array on the target is to avoid cosmetically unpleasant Moiré patterns on the TV display. When the analog

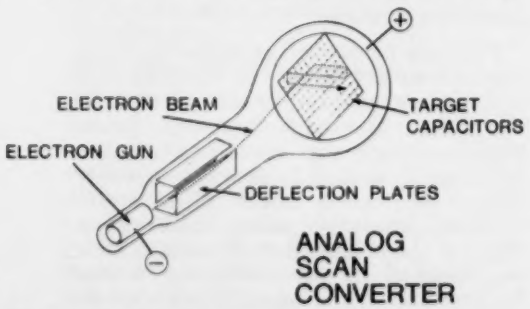

Figure 11. Anatomy of an Analog Scan Converter.

scan converter is properly focused (in its "read" mode) the pattern of the capacitors on the target can be seen as a crosshatch on the viewing TV (See Section 7.4.1).

The gray scale characteristics of the scan converter should also be periodically verified by the clinical operators. This should be done in conjunction with a check of the photographic hardcopy technique (See Section 7.4.2).

6.5 Digital Scan Converter

A digital scan converter is a scan converter built with solid state computer logic and memory circuits. Since in a digital scan converter the image information is stored as a set of numbers, both the patient cross-section in the scan plane and the image must be divided into corresponding arrays (square or rectangular) of little square picture elements called pixels. Usually the size of the pixels is so small that the digital nature of the image does not seriously affect the cosmetic appearance of the image data. Certainly the pixel size is smaller than the axial resolution of the transducer so the transducer, as usual, is the limiting factor in spacial image resolution. Digital images are usually specified by the number of pixels in the horizontal and vertical directions (e.g., 512 x 512, 400 x 512, 360 x 360, etc.). Digital scan converters do not suffer from the focusing, image volatility, limited life, and dynamic range problems associated with analog scan converters.

Commercial B-scanners which are equipped with digital scan converters usually have several operator selectable variables which have great value. The operator can choose between several different methods of converting the received echo amplitude information to the numbers stored in the computer memory (pre-processing). The operator can also choose between several different methods of assigning the display shades of gray to the echo amplitudes stored in the computer memory (post-processing). The presence of these variables is a welcome (and belated) addition to our B-scanners. These variables give the operator the ability to change the latitude (or contrast) of the ultrasound image. Previous B-scanners did not allow this variation.

Pre-processing is any operation on the ultrasound data (amplitude or position data) before it is stored in memory (the scan converter). Post-processing is any operation on the ultrasound data after it is stored in memory. A simple analogy will illustrate the difference. When a snapshot of a landscape is taken, any operation (focusing, shutter speed, development) before getting a finished negative is "pre-processing". Any operation (enlarging, focusing enlarger, developing print) after obtaining the negative and before obtaining the photographic print is called post-processing. If the negative is not in focus or is grossly overexposed (bad pre-processing) then no amount of darkroom skill (post-processing) can give a good print. The point we should realize is that pre-processing is much more important than post-processing not only in this analogy but in the clinical use of these new selectable equipment variables. Put most of your emphasis on learning to properly use the pre-processing variables on your equipment.

For example, when the echo amplitudes are converted into the numbers stored in digital memory (pre-processing) then the echo amplitude resolution is irrevocably assigned (See Section 6.6 below for details). Also, in the author's opinion, as long as the digital memory and the display have the same number of gray levels (stored numbers for each pixel) we do not need more than one post-processing scheme (a linear one).

Fig. 12 shows two prone, transverse renal images produced with the first digital scan converter in diagnostic ultrasound developed

Figure 12. Transverse renal images from the first digital scan converter in diagnostic ultrasound. The image on the right represents one-half the left-hand image with a histogram equalization post-processed gray scale presentation.

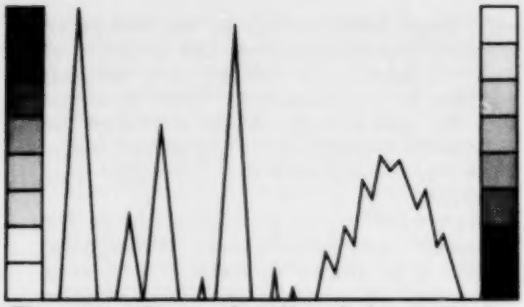

Figure 13. Gray scale coding of echo amplitudes.

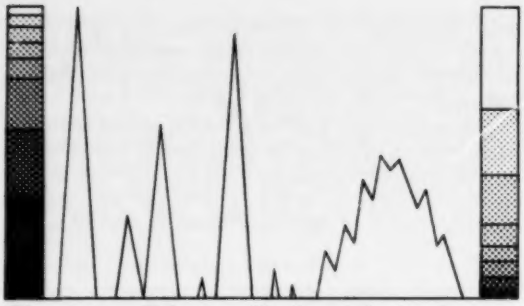

Figure 14. Echo amplitude resolution in gray scale displays.

in the author's laboratory under a National Science Foundation Grant (GJ-41682). These images have a 128 x 128 pixel format with 15 display shades of gray. The digital memory associated with each pixel is 8 bits deep (256 shades of gray). The real space dimensions of the pixels are 2 mm by 2 mm so that the axial resolution (at that time) of the transducer is the limiting factor in the image. Modern digital scan converters have much better spatial resolutions (more pixels in the image), but they also have much less echo amplitude resolution due to their more limited range of gray levels in memory.

Digital scan converters have only recently been developed and they contain high technology. Specific quality assurance tests have not, as yet, been specified for monitoring their performance. The parameters that should be checked in the digital scan converters are: 1) correct functioning of the memory elements, 2) correct functioning of the analog to digital converters used to transform the image information into digital form, 3) presence of all shades of gray and 4) correct functioning of the digital to analog converters used to transform the digitally stored image into a video signal for the display TV, 5) the correct functioning of the selectable gray level assignment schemes (pre and post-processing) which come as a feature of the digital scan converter.

6.6 Gray Scale Display

When gray scale replaced bistable displays several important changes occurred in ultrasound imaging. In bistable displays strong interface (specular) echoes were imaged and diagnosis was made on the basis of organ size, shape and location. With gray scale displays weak internal (diffuse) echoes are imaged and both echo amplitude and echo spatial distributions became important in organ identification and tissue pathology localization. Also, the tedious compound scan necessary in the search for specular echoes was replaced by the simple linear scan sufficient to detect the omnidirectional diffuse echoes.

When echo amplitude is encoded into shades of gray certain tradeoffs in echo amplitude resolution are inevitable. This is an important consideration in future equipment development and will be developed here to aid users in selecting between the new pre-processing schemes available in modern equipment.

Fig. 13 demonstrates the coding of echo amplitudes into eight shades of gray. On the left is the black on white display mode where the darker shades of gray represent higher amplitude echoes. On the right is the white on black display mode where the lighter shades of gray represent higher amplitude echoes. Each received echo is coded into a shade of gray in memory (the scan converter) depending on which shade of gray represents its peak amplitude. Each shade of gray represents an equal range of echo amplitudes. Once the echo is changed into a gray level then we do not know exactly what its exact amplitude was, only that the amplitude was contained in the range of echo amplitudes corresponding to that gray level.

Fig. 14 shows two white on black gray scales. The one on the left has more shades of gray at the high echo amplitudes. The one on the right has more shades of gray at the low echo amplitudes. For the right hand set of gray levels a small change in amplitude of a low amplitude echo will result in a change of display gray level. We, thus, say that this right hand set of gray levels has high echo amplitude resolution for low amplitude echoes and low echo amplitude resolution for high amplitude echoes. Put another way, each dark shade of gray represents a much smaller range of echo amplitudes.

The right hand set of gray levels in Fig. 14 represents the actual situation in our gray scale equipment. In the first gray scale units the unique gray level scheme was experimentally determined. This past situation in diagnostic ultrasound was analogous to the purchase of a general purpose x-ray generator which allows selection of any mA, time or mAs, but has only one possible KVp. Since

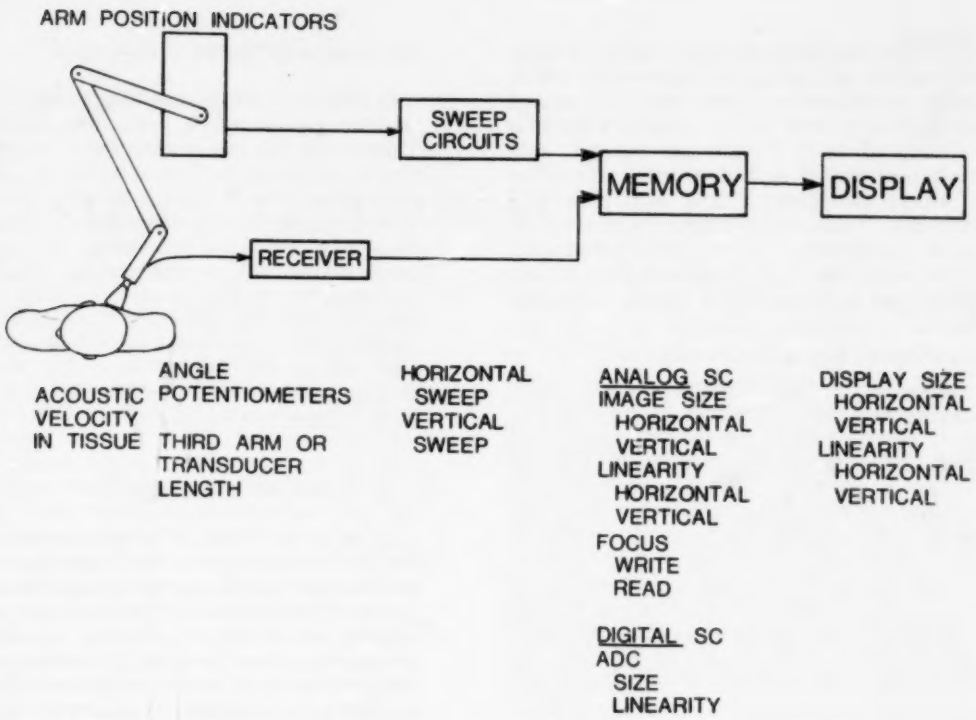

Figure 15. B-mode registration and image size variables.

KVp controls image latitude (or contrast) and patient penetration, only one contrast (latitude) range is possible with this machine, as was the case with the first ultrasound gray scale units.

In the use of our B-scanners we can change patient penetration by changing transducers (lower frequencies have greater penetration). But, up until the use of digital scan converters we, as users, had no way to vary the latitude (or contrast) of the displayed image. It stands to reason that different parts of anatomy or different disease conditions probably require different degrees of contrast and amplitude resolution in the displayed echo amplitudes in order to properly present the echo information for diagnosis. Now by selecting among the available pre-processing schemes we can control the latitude and amplitude resolution of the gray scale in the image. Our B-scanners, like the x-ray generator now equipped with a selectable KVp, will be even more useful for imaging various parts of patient anatomy and diagnosing specific tissue pathologies.

At present, the same number of shades of gray are displayed as are stored in the digital scan converter. Due to the flexibility of digital memory the gray level capacity of the digital memory is unlimited. The gray level capacity of digital scan converters should be increased. The benefits of increased digital memory size would include: more echo amplitude resolution in the information stored in memory; less dependence on the specific pre-processing scheme chosen; improved system data flow, without loss of resolution, because the memory dynamic range would be better matched to the received echo dynamic range and; with more information stored in memory, post-processing (data manipulation after the patient has gone home) is a more valid procedure.

6.7 B-Mode Registration

In order that the position of reflectors in the patient cross-section be properly represented in the ultrasound image, proper B-mode registration is essential. If the B-mode registration is not properly set, then the exact position of the reflector in the image will depend upon the position and angulation of the transducer (misregistration). Thus, linear scans will have a distortion in distance and compound scans will suffer a blurring effect because the same reflector is placed in different image locations for each "pass".

Fig. 15 indicates the B-mode registration and image size variables normally present in a contact B-scanner. The critical components in the B-scan equipment for determining the B-mode registration are: 1) the angle sensing devices which are located in the scanning arm joints and which track the xy position and angulation of the transducer and 2) the velocity circuits in the equipment (both

horizontal and vertical sweep circuits or their equivalents in digital scan converters) which represent the motion of the pulse of ultrasound through the body with the characteristic velocity of 1540 meters per second. Any maladjustment or lack of calibration in either of these two components will result in improper B-mode registration. At present, B-mode registration can be quite adequately tested with the AIUM 100mm Test Object whose use is described in detail in Section 7.4.4.

6.8 Display Size and Linearity

Improper B-mode registration will affect display size and linearity. There are also other components of the B-mode equipment (Fig. 15) which will affect the display size and linearity: 1) the x and y amplification circuits, for the analog scan converter, 2) the focus circuits for analog scan converters, 3) the x and y position analog to digital converters for the digital scan converter, 4) the x and y position digital to analog converters in the digital scan converter, 5) the horizontal and vertical size adjustments for viewing and hardcopy T.V.'s, 6) the horizontal and vertical linearity circuits in the hardcopy and viewing TV's. Miscalibration of any of these components will affect display size and linearity **(but will not affect proper B-mode registration)**. The display size and linearity should be checked at a less frequent interval than the B-mode registration.

In order to make proper distance measurements from ultrasound images and to be unaffected by display size and linearity considerations, the operator should make proper use of the 1 cm depth marker dots available on all modern equipment (See Section 4.2.2).

6.9 Document System Performance

In Section 7.5 suggested log sheets for the routine performance tests are included. These should be copied and used to record the results of the tests. This is essential data. It establishes a performance baseline for most of the important components in the equipment. Future questions concerning the proper performance of a component can easily be answered by referring to this data. Information concerning long or short term drifts in performance, acceptable levels of performance and component failure rate can also be determined from a properly maintained performance test log book.

6.10 Document System Repair

A log book of repairs on equipment should be properly maintained. Document each service problem by three separate types of entries in the service log book: 1) the person reporting the malfunction, date and description of the problem, 2) service person, date, action taken and results, and 3) person rechecking equipment, date, result of test. These three entries in the service log constitute a **complete** record of the event. A sample suggested service log sheet is shown in Section 7.6.

Any adjustment to the equipment (outside of front knob adjustments) made by anybody in your institution (physician, technologist, physicist or engineer) should also be recorded in the repair log. By having complete repair and adjustment records on equipment, one may be able to identify trends of problems leading to breakdowns that require major service.

7

ROUTINE PERFORMANCE TESTS

7.1 Introduction

The proper performance of an imaging system (ultrasound, x-ray, nuclear, thermographic, etc.) depends upon the proper performance of the total system and each sub-system (display, memory, receiver, arm registration circuits, sweep circuits, etc.). Desirable performance tests are those for total performance or specific to one sub-system. To be useful these tests must also be non-invasive (not opening the electronics and injecting signals between component circuits or measuring voltages at test points). This may be accomplished by using test objects or phantoms or by using a test signal (which mimics echoes of certain characteristics) at the front end of the system — the electrical connector to which the transducer attaches. Thus, desirable performance tests utilize the acquisition of scan data from known test objects (or the use of an electronic signal to mimic scan data from a known test object) and measurements from the resultant image of this known test object. Well designed test objects can give specific information concerning performance without the use of invasive testing procedures.

A **phantom** is a device which is specifically fabricated to be equivalent to human tissue in terms of the final medical image. It is used in situations where a patient scan is necessary but not practical or desirable (such as in x-ray). Another important feature of a phantom is reproducibility. A **test object** is a device specifically fabricated to test one or more parameters of the equipment. In no way is it meant to be equivalent to human tissue or to produce an image which resembles a patient scan. Test objects are frequently used in equipment performance tests (nuclear medicine field flood, x-ray step wedge, etc.). Test objects are reproducible and standardizable.

The characteristics (parameters) of both test objects and/or phantoms should be easily verifiable by independent tests, preferably by comparison with available secondary standards. For example, the distance between the reflectors in a test object can be verified by measurement with a ruler (secondary standard) provided the test object is not opaque. The acoustic velocity of the medium inside the test object can be verified by using two reflectors and measuring the distance between them (distance standard) and the time interval between received echoes from them (time or frequency standard). The attenuation of the test object medium for a given transducer can be roughly measured by using two identical reflectors inside the test object and measuring the distance between them and the difference in amplitudes of the received echoes (by use of a calibrated attenuator). More precise measurement of attenuation requires corrections for beam softening (change in pulse frequency spectrum due to increased absorption of higher frequencies) and the variation of echo strength for different positions in the transducer beam pattern.

If a performance test is failed by a system, then either the test object (or phantom) parameters, the testing procedure, or the system (or sub-system) performance is suspect. If the test object parameters can be verified independently and the testing procedure is a universally adopted one, then the only conclusion left is that the imaging system is not performing properly. Thus, independent verification of the test object (phantom) is important because it permits a physician or technologist to make correct technical statements about system performance.

The tests given below are divided into five sections. The purpose section clearly defines the system functions monitored by the test. All necessary materials are listed in the materials section. The procedure section covers the general instructions for the test. In the measurement section the exact measurement protocol and some discussion of possible measurement results are given. The last section is most important because it specifies the steps necessary to remedy any system malfunctions. The "action levels" are the values measured in the test which are believed to indicate bad performance. The "action" is the procedure which is necessary to correct this bad performance.

7.2 AIUM 100mm Test Object

The AIUM 100mm Test Object is described in detail in the AIUM Bulletin, Reflections, April, 1975. The AIUM 100mm Test Object

standard is reproduced in Reference Section 9.2. This description of the 100mm test object may also be obtained from the AIUM Executive Office, 6161 N. May Ave., Suite 45W, Oklahoma City, Oklahoma 73112.

There are several commercial versions of this test object. Important considerations in selecting among these include quality of manufacture, adequate instructions and the provision to permit the expansion of the enclosed liquid without rupturing the test tank. Expansion bellows, a rubber membrane or trapped air will allow the liquid to expand with temperature changes without putting pressure on the Plexiglas joints of the tank. A list of commercial suppliers is given in Reference Section 9.3.

When the test object is received, perform a simple acceptance test. Check for leaks since the test object operation can be compromised by leaks. By visual observation verify that the 3/4 mm stainless steel rods are all perfectly straight and parallel to one another. If they appear straight and parallel the test object has suffered no obvious damage in shipment. With a ruler convince yourself the rods are positioned to within ± 1 mm of their specified locations. (The AIUM standard specifies ± 1/4 mm which is difficult to check without the proper equipment.) Once the position accuracy of the rods has been established, the only unknown remaining is the acoustic velocity of the enclosed liquid. This is to be checked each time the test object is used following the detailed procedure described in Section 7.3.

Examine the outside scanning surfaces of the test object. Any air bubbles trapped under the Teflon strip must be removed or they will interfere with the operation of the test object. Push them to the edge of the Teflon strip with your fingernail, or puncture the Teflon with a pin and force the air out through the pinhole.

For each ultrasound B-scanner to be tested choose one transducer (standard transducer) **to be used consistently in all tests**. To use the AIUM 100mm Test Object, experiment with different kinds of coupling media until you find one which suits you best. Always use generous amounts of coupling medium in all tests with the test object. If you do decide to change the coupling medium, be aware there may be a change in the results of the A-mode sensitivity test (Section 7.4.3).

The formation of algae may occur inside the test tank. To prevent this you can add a retardant (17) to the liquid or you can simply store the test object in a cabinet or other dark enclosure. Store the test object in the clinical room so that it is always immediately available for quick checks.

When scanning the test object always put it on a flat stable surface. If you place the test object on the patient couch (Fig. 16), when the transducer is scanned across the test object's surface the test object will move on the mattress. Motion of the test object means that the rods are not always in the same position in space. This is poor practice because the basic principle of the test object is that the rods have a constant position in space.

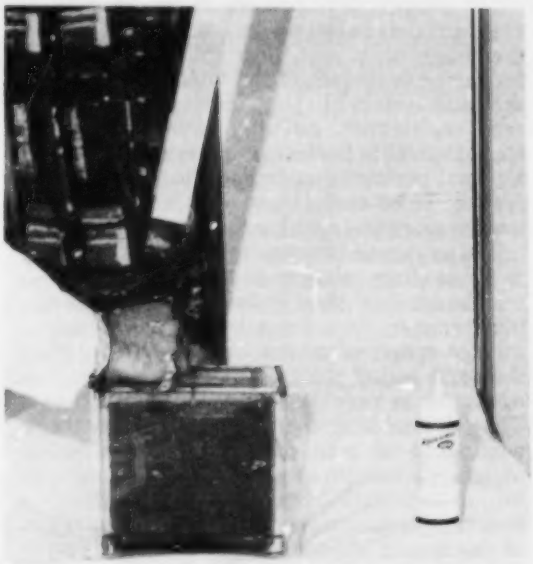

Figure 16. Improper use of AIUM 100mm Test Object.

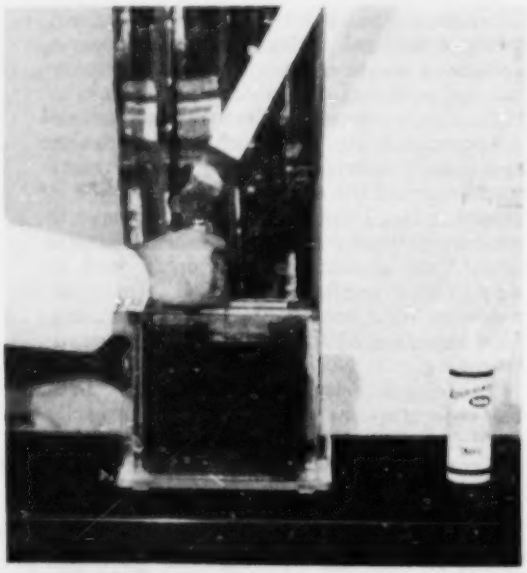

Figure 17. Proper use of the AIUM 100mm Test Object.

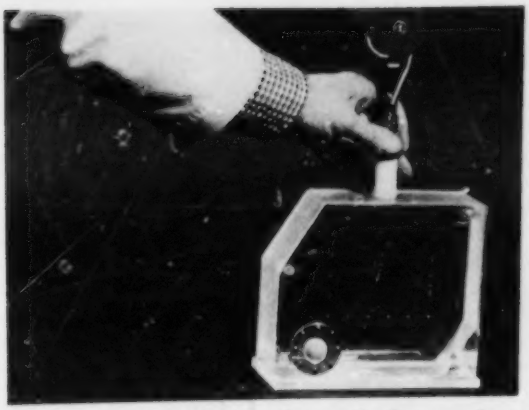

Figure 18. Positioning the vertical scan plane prior to scanning.

When scanning the test object the scan plane (containing the three sections of the B-scanner articulated arm and the path of the unrefracted ultrasound beam) must be perpendicular to the 3/4 mm stainless steel rods in the test object. This scan plane orientation will also ensure that the transducer output surface is in good contact with the flat rigid test object scanning surfaces. The good contact is essential for penetration into the test object. The easiest way to align the scan arm and test object is to use the following procedure: position the test object and articulated arm so that the transducer is able to contact all of the required scan surfaces. (If the articulated arm is too close to the test object the proximal vertical surface is not accessible; if they are too far apart the distal vertical surface is not accessible). Adjust the articulated arm so that the scan plane is vertical (Fig. 18). Now keep repositioning the test object until the transducer can touch the middle (in width) of the top and two vertical surfaces (Fig. 19 and Fig. 20). This is a trial and error procedure which is easily mastered.

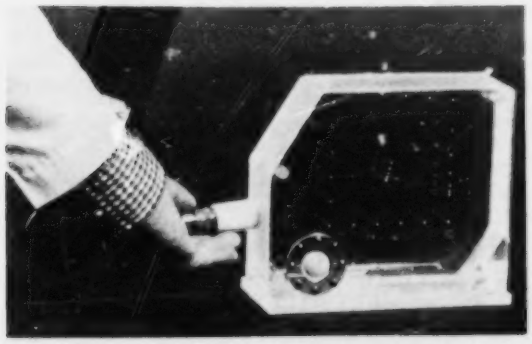

Figure 19. Testing transducer contact with the proximal scanning surface.

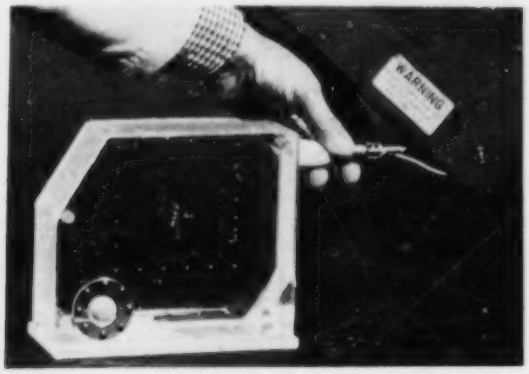

Figure 20. Testing transducer contact with the distal scanning surface.

7.2.1 Test Object Liquid

As previously mentioned it is important that the AIUM 100mm Test Object have an enclosed liquid whose acoustic velocity is 1540 meters/second. It is **not** possible to correct scans of the AIUM 100mm test object afterwards for velocity errors. The acoustic velocity of the enclosed liquid **must** be 1540m/sec for the results of the B-mode registration test given below to be correct. If the enclosed liquid has a velocity different from 1540 meters per second, then an apparent misregistration error will be measured. For example, when the acoustic velocity of the enclosed liquid is lower than 1540 meters per second, the travel time of the ultrasound pulse is longer than it would be if the liquid had the velocity of 1540 meters per second. The position of the rod in the image is, thus, at a further distance from the transducer than it really should be. Since the effect is cumulative with distance the largest error will come from the rod farthest from the two scanning surfaces (typically 14 cm). For a velocity error of 1%, there is an apparent misregistration of 2 mm at 14 cm. A velocity error of 2.5% corresponds to an apparent misregistration of 5 mm at 14 cm (18).

7.2.2 Ethylene Glycol-Water Mixtures

Recently, it has been found that pure reagent grade ethylene glycol-distilled, degassed water mixtures have many properties that make them suitable for use in ultrasound test objects (18). These properties include: a wide range of attainable velocities which includes 1540 meters/second, a low temperature coefficient at room temperature, long term stability in test objects, low attenuation of diagnostic ultrasound energy and transparency to visible light.

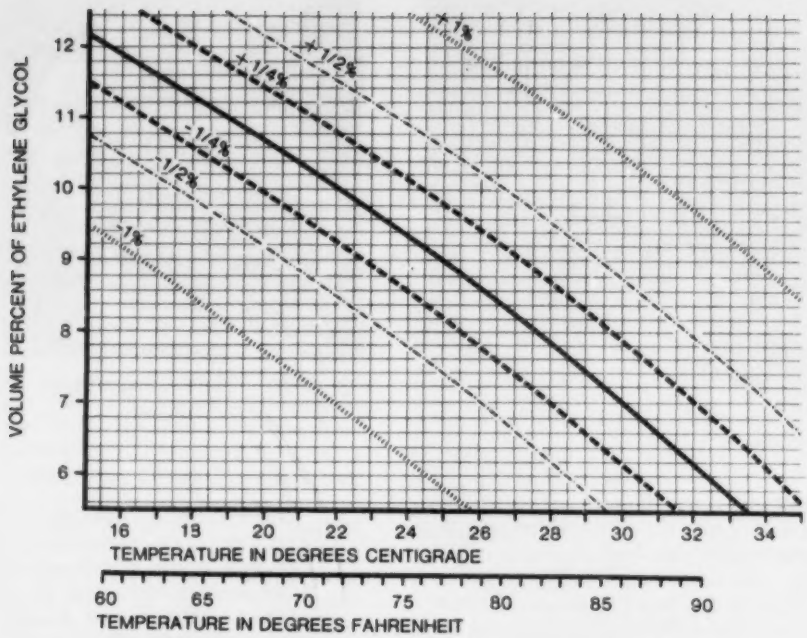

Figure 21. Required volume percentage of ethylene glycol to attain an acoustic velocity of 1540 meters/second as a function of temperature.

The question asked by the clinical user is, "What percentage by volume of ethylene glycol should be used in order to obtain an acoustic velocity of 1540 meters per second if the temperature is known in my clinical laboratory?" To answer this question the data in Fig. 21 was calculated using measured velocity and temperature coefficient data (18). The solid curve represents the volume percentage of ethylene glycol necessary to obtain an acoustic velocity of 1540 meters per second for temperatures in the range of 16 to 33°C. Also shown in Fig. 21 are the curves for velocities ± 1/4%, ± 1/2% and ± 1% deviant from 1540 meters per second.

To measure the temperature in your clinic simply place a cup of water with a thermometer in it in the spot the 100mm test object will be stored. Make certain the spot is not near a radiator or in the direct path of heating or cooling air. Measuring the temperature with a thermometer alone (in air) is not proper technique and can lead to serious temperature errors.

7.3 Calibration Check of Test Object Liquid Acoustic Velocity

Purpose

To verify that the liquid in the AIUM 100mm Test Object does indeed have an acoustic velocity of 1540 meters/second and, that all B-mode registration tests made using this test object are valid.

Materials

AIUM 100mm Test Object
Hardcopy Film
Standard Transducer
Digital Calipers or Rule or
Gerber Variable Scale

Procedure

Place the AIUM 100mm Test Object on a flat stable surface with swept gain (time varying gain) off, and the overall gain set to a predetermined level. Verify that the stainless steel rods are straight, parallel and the correct distance apart. Use the bistable mode of pre-processing and display. Perform a linear scan on a side (vertical) surface of the test tank and obtain images of the 2 cm horizontal rod group (Fig. 22). Place 1 cm depth marker dots just above or below the images of the 2 cm horizontal rod group. Take hardcopy. Fig. 23 shows a typical image of this horizontal scan.

When testing the acoustic velocity of the enclosed liquid, the highest measurement accuracy will be obtained from a linear scan on the side of the test object and the images of the 2 cm horizontal group of rods (rather than the vertical 2 cm rods) (18). Scan from the side of the test tank that is farthest from the 2 cm horizontal group of wires. The reason for using the horizontal rods is that if the vertical rods are used the images of rods closest to the transducer face are **not** placed in their correct spatial position in the image. This is

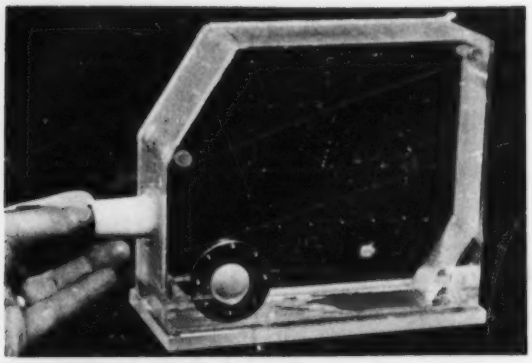

Figure 22. Scanning of the 2 cm horizontal rod group to check the enclosed liquid velocity.

due to near field diffraction effects. The 2 cm vertical group of wires has its top rods close to the transducer face. Errors as large as 1% in the velocity determination can be obtained from using this vertical rod group. The 5 to 6 cm separation between the horizontal rods and the scanned side of the test tank should reduce the near field diffraction errors sufficiently.

Measurement

When measuring distance on the image between the depth marker dots, make the measurement between the centers of the dots. When measuring distances between rods take the location of the rod in the image to be the center of the proximal (toward transducer) edge of the line in the image.

In the horizontal linear scan image, verify that the 10 cm long, 2 cm horizontal rod group has the same length as 10 cm measured with the horizontal depth marker dots. For B-scanners with analog scan converters a distance measurement must be made on the image. The ruler with the finest gradations will give the highest accuracy. For equipment with digital scan converters the digital calipers may be used. First, verify that the digital calipers are working properly by measuring the distance between 10 cm on the horizontal depth marker dots. If a distance value of 10.0 cm is indicated the calipers are functioning correctly. Then place digital caliper cursors similarly on both end rod images (the two rods at the ends of the horizontal 10 cm group) and measure the distance across the group of rods. Fig. 23 demonstrates proper use of the digital calipers (note black square cursors on two end rods). The result of the digital caliper measurement appears on the image in the lower right on the third line from the bottom.

It should be noted here that any miscalibration of the horizontal sweep circuit will not affect this measurement. Non-linearities in the display size can affect this

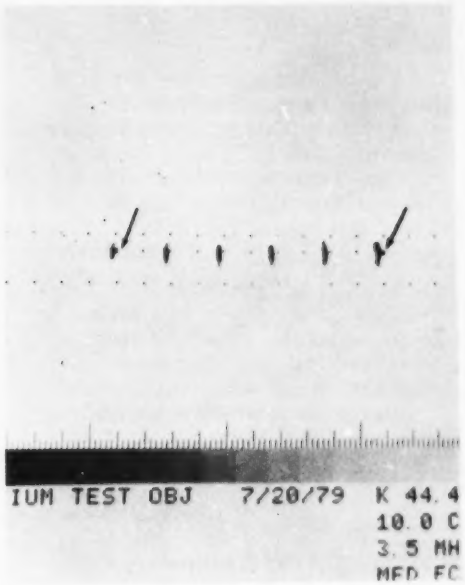

Figure 23. Image of the 2 cm horizontal rod group for checking enclosed liquid velocity. The transducer was scanning from the right. The cursors are positioned at the echo leading edge.

measurement if poor technique is used in the measurement. Make certain the lines in the image have clearly defined leading edges. Always place the depth marker dots in the image close to the images of the horizontal rods and when making measurements from the image always use the 1 cm depth marker dots closest to the end rods used for the rod distance measurement.

Action Levels and Action

In the horizontal linear scan image the 10 cm image distance of the horizontal 2 cm rods and the image distance between 10 (11 for purists) horizontal depth dots should, with extreme measurement care, agree to within 1% (1 mm over 10 cm). If they don't then either the liquid in your test object has become corrupted (changed in acoustic velocity), the temperature of your laboratory has changed considerably (thus affecting the velocity) or the error is with the equipment. Since the depth marker dots are generated by a highly stable circuit, suspect the liquid in the test object.

With care the acoustic velocity measurement can detect velocity changes of 1%. Fig. 24 is the result of a velocity measurement from a test object whose enclosed liquid was intentionally made 1% lower than 1540 m/sec in velocity. The digital caliper measurement indicates an image distance of 10.1 cm between the end rods of the horizontal 10 cm group of rods. A distance of 10.1 cm indicates

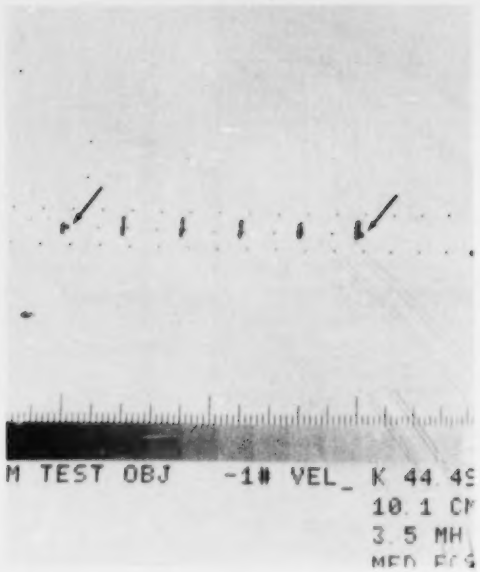

Figure 24. Image of the 2 cm horizontal rod group showing an acoustic velocity error of -1%. The transducer was scanning from the right. The cursors are positioned at the echo leading edge.

a 1% (1 mm in 100 mm) velocity error. The 1% error can also be detected with a ruler measurement from this figure. The discrepancy in image distance between the imaged rods and 10 cm as indicated by the depth marker dots is about equal to the width of the black cursor square in the image.

In the clinical setting it is not always possible to perform measurements, such as this one, to the utmost precision and accuracy. If the multi-image hardcopy used has six or nine images on an 8 × 10 inch sheet of film, then the small size of the image makes distance measurements difficult. With some trial and error practice you must decide to what accuracy (in percent) you can confidently measure the acoustic velocity. This will be your error margin in determining if your B-scanner has less than 5 mm B-mode misregistration. (See Section 7.4.4.) Remember that for a rod 14 cm distant from the scanning surface a 1% error in velocity gives an apparent 2 mm misregistration, a 2% error in velocity gives an apparent 4 mm misregistration, and so on.

For example, in evaluating the results of the B-mode registration test given in Section 7.4.4., if your measurement uncertainty is 2% then, on average, your action level should be 7 mm misregistration (5 + 4/2). If your measurement uncertainty is 3% then, on average, your action level should be 8 mm misregistration (5 + 6/2).

Some 100 mm test objects have an internal thermometer. A temperature check of the enclosed liquid is to be made before use. Be aware that this is an **indirect** check of the acoustic velocity. That is, correct as long as the composition (of the liquid) remains constant. The author prefers the **direct** check of acoustic velocity as described above.

The point here is that there is a potential variable in your measuring instrument (the acoustic velocity of the liquid in the test object) — it must be checked each time you use the test object to verify B-mode registration. If there is no agreement between these rods and the depth marker dots then either remix the liquid, being careful to use degassed, distilled water (aged at least two days to allow trapped gas to equilibrate with the atmosphere), borrow another test object, or ask your service person to check the equipment and then redo the test. This test **must be passed** for you to believe (and hold as the gospel!) any measurement of B-mode registration made with the test object.

7.4 Routine Performance Tests

The tests presented here are a compromise between completeness and ease of use. If a complete set of tests were specified to measure every parameter of the imaging system then performing and analyzing them routinely would present a burden and soon they would not be done at all. Only the most important system parameters are checked with this set of tests. For example, display size and linearity are not checked because: 1) analyzing the test images is time consuming and 2) if depth marker dots are used routinely and properly then these two variables will have minimum effect on the resultant diagnosis.

In the future, new test objects, phantoms and testing procedures will be developed. At the present time these tests are the best ones available for routine checking of system performance.

The Performance Tests should be executed in the order given below.

7.4.1 Analog Scan Converter Test

Purpose

A check of proper focus of the analog scan converter tube.

Materials

Hardcopy film

Procedure

After one hour warmup, generate a fresh gray bar on the hardcopy display. Set the zoom control on the scan converter to maximum magnification and then examine closely all areas of the picture. A background crosshatch pattern (the analog scan converter target capacitor

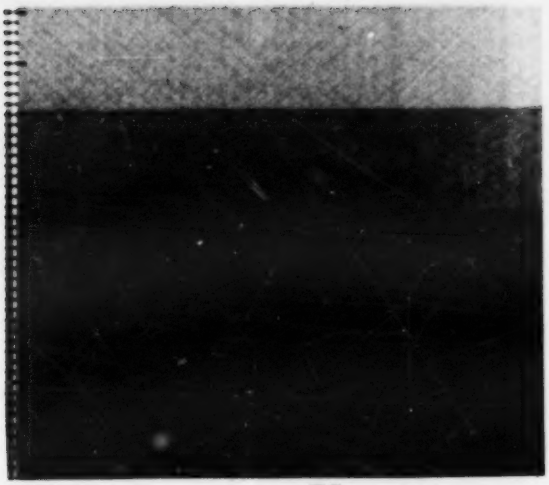

Figure 25. The crosshatch pattern of a focused Analog Scan Converter.

array) at 45° to TV scan lines, should be visible in all areas of the picture. If necessary, use the contrast enhance control to make the crosshatch pattern more visible. Fig. 25 shows a typical crosshatch pattern.

The depth dot markers in the gray bar pattern of some equipment need not be in proper focus. In fact, older analog scan converters tend to suffer from large blurred depth marker dots.

Measurement

After every service call, and in subsequent routine tests the crosshatch pattern should be verified. It is not necessary to take a picture each time.

This test is not foolproof. If this test is failed (no crosshatch pattern) the analog scan converter **will not** function well in patient scans. However, there are instances where a sharp crosshatch pattern may be obtained from this test (e.g., scan converter focused incorrectly on acceleration grid or write focus out of calibration — this procedure only tests the read focus) and yet patient scans will be out-of-focus. The **final** check of the analog scan converter is a sharply focused patient scan, AIUM 100mm Test Object or preferably, an appropriate ultrasound tissue phantom. Routine standing liver scans should be avoided due to unanswered questions concerning the biological effects of diagnostic ultrasound.

Action Level and Action

If the crosshatch pattern is not visible in all portions of the picture, call the service person. If it is slightly visible proceed with the other tests so that he can fix "everything" when he comes. If visibility is poor perform only the A-mode tests before he comes.

7.4.2 Gray Scale Test

Purpose

A check of scan converter operation, T.V. operation and proper hardcopy photographic technique for recording **all** of the gray levels in an echogram.

Materials

Hardcopy film. (Use the same hardcopy film and x-ray film processor used for patient scans.)

Procedure

Make certain the brightness and contrast controls on the hardcopy TV monitor are set at their usual levels. This test is only to be performed with the gray scale display mode (black on white or white on black) used for your clinical images. Generate a new gray bar and take hardcopy. See Section 4.5.1. for details.

Measurement

In the gray bar hardcopy there should be a distinct and discernible difference between all the displayed shades of gray. The apparent nonuniformity of the gray bars near their edges is an edge enhancing perceptual phenomena called the Mach effect. (At the boundary between light and dark shades of gray, the light shade of gray appears lighter and the dark shades of gray appear darker.) A random splotchy appearance of the pattern (local areas of lighter or darker gray bars) is a characteristic of analog scan converters. This effect should not, however, change a shade of gray so that at any portion of the image it is lighter or darker than any adjacent shades of gray (at any point along their length).

Check to see that the correct number of gray levels are present and that the recorded shades of gray agree with previous documented results of this test.

Action Level and Action

If the gray levels are not the same as previously recorded, or if any are missing in the hardcopy, readjust the brightness and contrast controls on the hardcopy TV and take hardcopy. Try the brightness first since it is the least stable. Remember that the film and your eyes "see" the shades of gray differently. Thus, proceed in small steps, change only one control a small amount and then take a picture to see the effect in the hardcopy. If all of the shades of

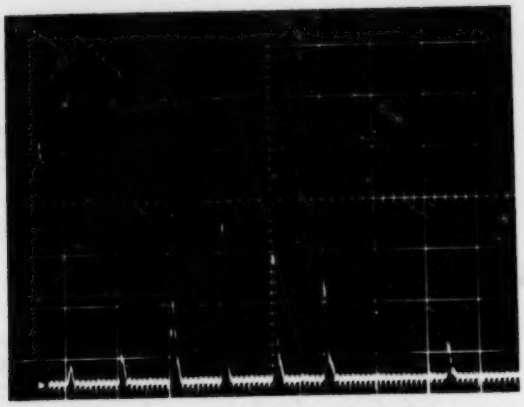

Figure 26. A-mode display of the vertical 2 cm rods. The last echo seen is the tank bottom.

gray do not record on the hardcopy with TV brightness and contrast adjustment, you may actually have an analog scan converter problem — call your service person.

7.4.3 A-Mode Test

Purpose

A check of the consistency of receiver gain (long term drift, sensitivity) and noise level.

Materials

AIUM 100mm Test Object
Hardcopy film for A-mode scope if desired and available.
Standard transducer

Procedure

Always use the same transducer for this test. Place the AIUM 100mm Test Object on a flat stable surface. Align the scanning arm and test object carefully so that the transducer face can be held exactly flat against and in the center of all windows of the test tank. Use plenty of coupling gel in all tests involving the test object.

There is some variability in this test due to operator scan technique. More or less

Figure 27. A-mode display of the vertical 2 cm rods. Distance markers have been turned off and baseline set on a graticule line.

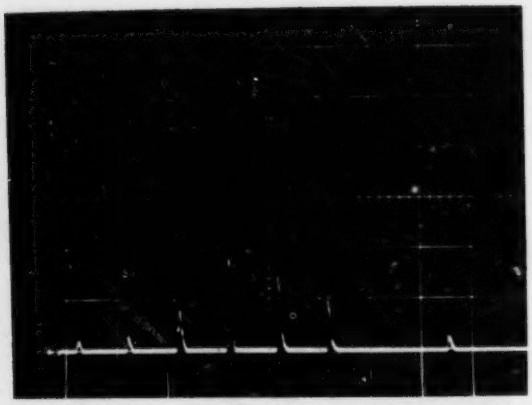

Figure 28. A-mode display of the vertical 2 cm rods. The system gain has been set for a 1 cm height echo from the last rod.

pressure on the transducer will change the thickness of the coupling gel layer. To minimize the variations always have the same operator perform this test. If in doubt perform the test three separate times and average the results.

Set all receiver controls (overall gain, TGC, etc.) to minimum gain. Set the output control (Picker) to midrange value (output to -24 dB on Searle Scanners). Place the transducer on the top surface of the test object and move it to visualize the vertical 2 cm spaced group on the A-mode display (Fig. 26). If possible turn off the A-mode distance markers. Position the A-mode baseline on a graticule line in the display (if you have one). Adjust the transducer position to maximize the echo from the bottom rod (Fig. 27). Note that the last echo seen on the A-mode trace in Fig. 27 is the tank bottom. The bottom rod echo is the last echo in the set of 2 cm apart echoes. Using the A-mode display find the overall gain setting to display a "one division" (you choose this, on the A-mode display or graticule) echo from this bottom rod (Fig. 28). In scanners with new 100 dB receivers it may be necessary to keep the gain at minimum and reduce the echo size with the output control. Take hardcopy if desired.

You may experience difficulty in positioning the A-mode baseline or in setting a "one-division" echo amplitude due to parallax effects. (Non parallel light rays.) The position of the A-mode baseline will appear to move in the display as you move your eye up and down. The camera eye is at a fixed angle, with practice you will learn how to see the display as the camera sees it. Another procedure to minimize parallax effects is to move your eye back from the display as far as you conveniently can.

Remove the transducer from the test object, wipe off the coupling medium but keep it connected to the scanner. Set the output to maximum and all receiver controls to maximum gain. Look for noise (grass) on the A-mode baseline (Fig. 29 shows low amplitude noise at high gain.) Turn back on the distance markers.

Measurement

Record the gain/output/attenuator settings necessary to display the "one division" echo from the bottom rod of the 2 cm spaced vertical group. If any other controls affect the echo height, then record them as well, e.g., A-mode gain on Picker scanners. Make certain that the height of the main bang (first large echo-like structure in A-mode) is the same in all future hardcopy.

In repeat tests the easiest procedure is to reproduce all recorded equipment "settings" and then try to demonstrate a 1 division high echo with transducer angulation.

Action Levels and Action

The gain required to display the bottom rod should not vary more than 6 dB or two output settings from test to test. If a slow steady increase in required gain (or increase in the required output setting) is necessary then notify your service person to check the receiver on his next service call. If more than a 6 dB change in gain or two output settings is required then call in your service person immediately.

There is another system variable, the vertical height (or gain) adjustment on the CRT display, which can also cause the echo height to change in the A-mode hardcopy. The consistency of the vertical gain on the CRT display is verified by checking the height of the main bang. The main bang should always have the same height on A-mode hardcopy.

The noise should not exceed a height specified by your service person (1 mm for Picker Scanners). If the noise is too high call in your service person.

In the future the receiver gain test will be replaced by a scan of maximum penetration of a stable tissue equivalent phantom.

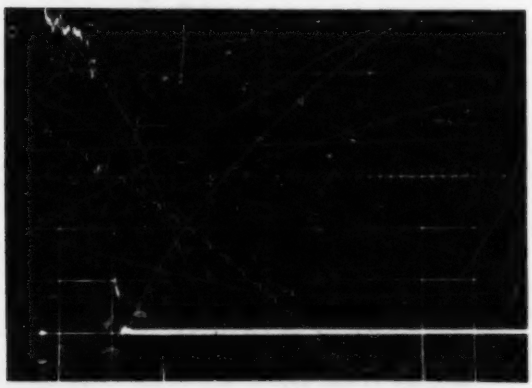

Figure 29. A-mode test for electrical noise. At maximum gain any electrical noise present will be visible on the A-mode baseline. This trace demonstrates low amplitude noise pulses.

7.4.4 B-Mode Registration Test

Purpose

To verify that a reflector in the body is placed in its proper anatomical location in the ultrasound image independent of the transducer position or angulation.

Materials

AIUM 100mm Test Object
Hardcopy film
Standard transducer
Digital Calipers or Ruler or
Gerber Variable Scale (Gerber Scientific Co., Hartford, Conn.)

Procedure

Verify the velocity of the test object liquid. (See Section 7.3) Place the AIUM 100mm Test Object on a flat stable surface. Use the bistable mode of pre-processing and display. Use the field size in which the rod pattern of the test object is the largest in the image (usually the 20 cm field or 2 cm/div). With swept gain off and the overall gain set at a predetermined value (and with other standard control settings), perform a linear scan on the top surface of the test object. On equipment with depth dot markers — drop vertical 1 cm dots just outside the 2 cm vertical group and horizontal 1 cm dots just below the 2 cm horizontal group.

Now add to the linear scan other linear scans from several sides of the test object tank. Readjust the gain or output if necessary. Do not perform so many scans that the crosses at the site of each rod become too numerous for analysis. A combination of scans from the horizontal (top) and vertical (side) surfaces is usually the most sensitive for detecting misregistration. The lines representing the rods of the test object should cross at their centers if the B-mode alignment (position and velocity circuits) are functioning properly (Fig. 30). Take hardcopy.

Perform this procedure several times to make certain that the results are consistent. It is possible to get varying results depending on scan technique and the quantity of coupling gel used. For example, the image shown in Fig. 31 was obtained immediately after the image in Fig. 30 with no change in the equipment or

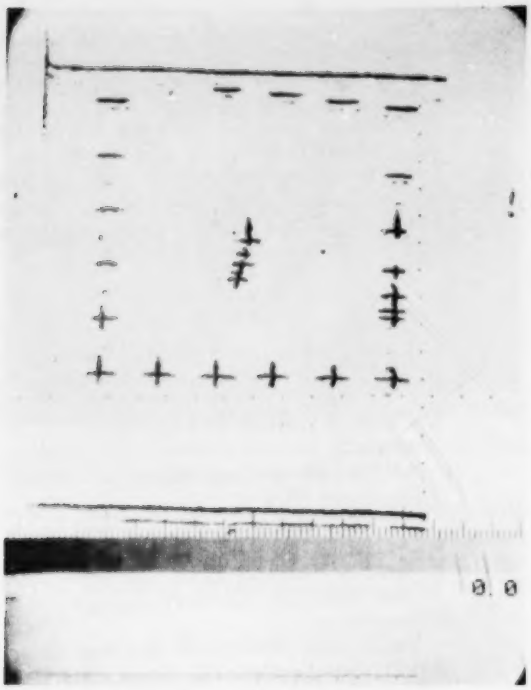

Figure 30. Image of AIUM 100mm Test Object.

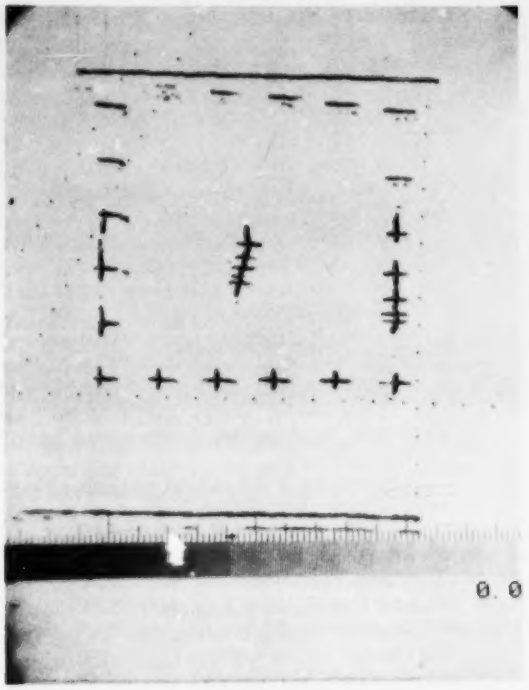

Figure 31. Another image of AIUM 100mm Test Object taken immediately after the one shown in Fig. 30.

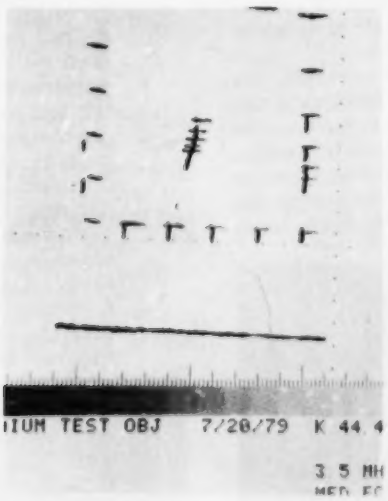

Figure 32. Image of AIUM 100mm Test Object demonstrating 7 mm misregistration.

gain settings. Choose the most reproducible image to measure.

Measurement

When measuring distance on the image between the depth marker dots use the centers of the dots. When measuring distances between rods (or the misregistration in a compound scan) take the location of the rod in the image to be the center of the proximal (toward transducer) edge of the line in the image.

In this test misregistration is defined as the maximum distance between two images of the same rod. In the compound

scan image look for the rod whose image deviates the most from a perfect cross. Measure the distance between the centers of the component lines using the appropriate 1 cm depth marker dots as a distance scale. Record the maximum distance. Fig. 30 shows good registration. Fig. 32 shows a 7 mm misregistration. See the discussion in Action Levels.

For equipment with digital scan converters the digital calipers may be used to measure the misregistration. Be certain to check the digital caliper measurement by using the 1 cm depth marker dots (See Section 4.2.2). Fig. 33 demonstrates the technique and 4 mm result.

An indication of the transducer lateral resolution may be obtained from its beam pattern. A linear scan of the vertical 2 cm rod group, with good scanning technique, gives a crude representation of the beam pattern. The length of the lines in the image indicates lateral resolution. Fig. 34

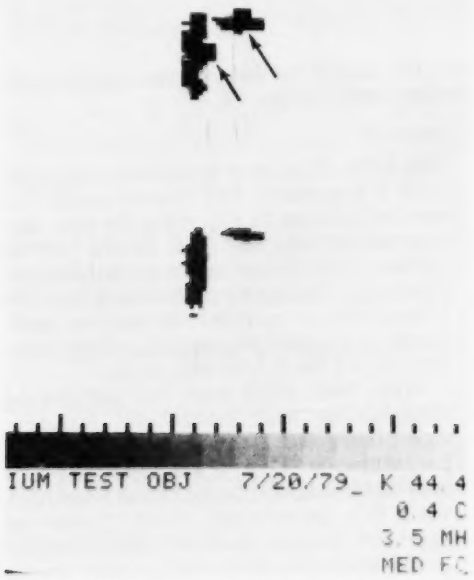

Figure 33. Technique of using digital calipers for measuring misregistration (arrows show cursors).

demonstrates the beam pattern of a 3.5 MHz short focus transducer. The shortest lines are at the focal region of the beam pattern. More accurate beam patterns may be obtained with other test objects (15).

Action Levels and Action

In the compound scan image, if the measured maximum misregistration is greater than 5 mm, call in your service person. If your test object velocity uncertainty is greater than 1%, use the modified action levels given in Section 7.3. Continue to take clinical scans but avoid compounding (compound scans). Also, either do distance measurements properly using the depth marker dots or **do not** make distance measurements until a satisfactory repair has been made.

7.4.5 Test of Transducer Axial Resolution

Purpose

To perform transducer acceptance test. To indicate the degree of axial resolution attainable in clinical scans. To check for consistency of the transducer axial resolution, since damage can degrade axial resolution markedly.

Materials

AIUM 100mm Test Object
Hardcopy film
Transducer

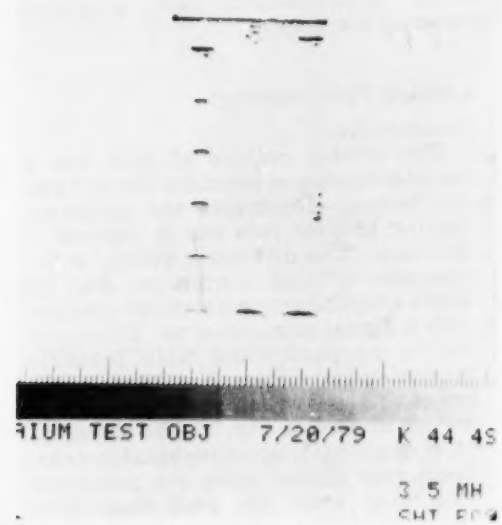

Figure 34. Indication of the beam pattern of a 3.5 MHz short focus transducer using a vertical linear scan of the 100mm test object.

Procedure

Place the AIUM 100mm Test Object on a flat stable surface. Use gray scale preprocessing and display. With swept gain (TGC) off and the overall gain set at a low level perform a linear scan on the top surface of the test object. Select the largest field size (magnification) with which the central complex of wires can be imaged. Determine the overall gain which images the largest number of rods. Note all gain

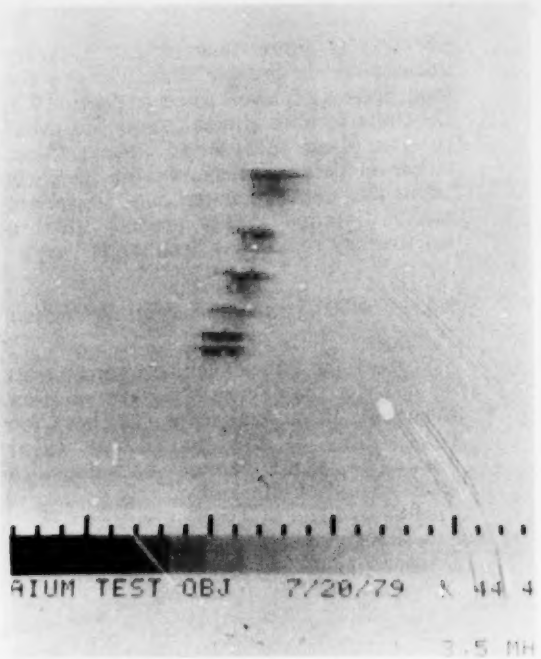

Figure 35. Axial resolution scan - gray scale pre-processing and display.

Figure 36. Axial resolution scan - bistable pre-processing and display.

settings. Take hardcopy.

Measurement

The central pattern of rods has a variable spacing of 5 mm (on top) to 1 mm (on bottom). Determine the minimum spacing between rods that is resolved in the image. This distance is defined as the resolution of that transducer. Fig. 35 shows a typical gray scale image obtained with a digital scan converter. This test is not to be performed with bistable processing and display. Fig. 36 shows the image obtained with the same transducer and set up used in Fig. 35. The measured axial resolution is less in the bistable mode. Since most clinical scans are performed with gray scale, the gray scale axial resolution is the relevant parameter to measure.

Action Levels and Action

Presently available clinical transducers should have an axial resolution between 1 and 2 mm. If in your acceptance test scans with a transducer you cannot attain this axial resolution by adjusting the gain and output control, then call in the service person — the transducer may be defective. Document the results of this test for each transducer in clinical service on each machine it is used on routinely. Store these test results for future reference.

This test need not be performed routinely on each transducer, but only when there is a question concerning the performance of a transducer. If you previously attained proper axial resolution with this transducer, then it may be damaged. Repeat the axial resolution test on the same machine with another transducer. If both transducers fail this test, then call in the service person. If only the first failed the test, then replace the defective transducer. Or test the same transducer on two machines to find where the fault lies — transducer or machine.

7.5 Performance Tests Worksheet

Performed By _____ Date _____

B-Scanner Manufacturer _____ Model _____

Serial Number (if more than one at facility) _____

Transducer Model _____ Serial Number _____

Frequency _____ , Diameter _____ . Focus _____

TEST OF TEST OBJECT LIQUID VELOCITY

AIUM 100mm Test Object visually inspected ☐

Bistable mode used ☐

Settings required ☐

Gain _____, Output _____, Attenuator _____,

Other _____, Other _____

Measured length of 2 cm horizontal rod group X = _____ cm

Test Passed - less than 1% difference ($9.9 \leq X \leq 10.1$) ☐

Test Failed - more than 1% difference ($9.9 > X$ or $X > 10.1$) ☐

Action Taken _____

SCAN CONVERTER TEST (Analog Scan Converter)

Instrument warmed up ☐

Hardcopy taken after service call ☐

Crosshatch pattern ☐

In focus ☐

Out of focus ☐

Test failed - service person called ☐

GRAY SCALE TEST

M-mode sweep set to standard setting (where applicable) ☐

New gray bar generated, hardcopy taken immediately ☐

Gray levels same as previous picture ☐

T.V. readjusted to get acceptable gray levels ☐

Hardcopy camera readjusted to get acceptable gray levels ☐

Test failed - service person called ☐

A-MODE TEST

"One Division" echo is _____ mm high in hardcopy

Settings required

Gain _____, Output _____, Attenuator _____

Other _____, Other _____

Receiver set to maximum gain ☐

Hardcopy taken of baseline noise at full gain ☐

Height of noise is _____ mm

Test failed - service person called ☐

Gain changed more than 6 dB ☐

Excess noise ☐

B-MODE REGISTRATION TEST

B-Scanner Serial Number _____

Settings required

Gain _____, Output _____, Attenuator _____,

Other _____, Other _____

Hardcopy taken ☐

Standard transducer used (Serial Number _____) ☐

Registration error (distance between center of lines) _____ mm

Test failed (greater than 5 mm) - service person called ☐

TRANSDUCER AXIAL RESOLUTION TEST

Frequency _____, Diameter _____

Serial Number _____

B-Scanner (Serial Number) _____

Setting used

Gain _____, Output _____, Attenuator _____,

Pre-processing _____, Post-processing _____,

Other _____, Other _____

Hardcopy taken and filed ☐

Axial resolution measured ☐

TRANSDUCER AXIAL RESOLUTION TEST

Frequency _____, Diameter _____,

Serial Number _____

B-Scanner (Serial Number) _____

Setting used

Gain _____, Output _____, Attenuator _____,

Pre-processing _____, Post-processing _____,

Other _____, Other _____

Hardcopy taken and filed ☐

Axial resolution measured ☐

TRANSDUCER AXIAL RESOLUTION TEST

Frequency _____, Diameter _____

Serial Number _____

B-Scanner (Serial Number) _____

Setting used

Gain _____, Output _____, Attenuator _____

Pre-processing _____, Post-processing _____,

Other _____, Other _____

Hardcopy taken and filed ☐

Axial resolution measured ☐

7.6 Sample Service Log

DATE _____ TIME_____ PERSON REPORTING _____
DESCRIPTION OF CONDITION

DATE _____ TIME_____ SERVICE PERSON _____
WORK ORDER # _____ INVOICE #_____ APPROVED BY_____
DESCRIPTION OF SERVICE PERFORMED

DATE _____ TIME_____ PERSON CHECKING _____
CONDITION OF EQUIPMENT AFTER SERVICE CALL

_____

DATE _____ TIME_____ PERSON REPORTING _____
DESCRIPTION OF CONDITION

DATE _____ TIME_____ SERVICE PERSON _____

WORK ORDER # _____ INVOICE #_____ APPROVED BY_____
DESCRIPTION OF SERVICE PERFORMED

DATE _____ TIME_____ PERSON CHECKING _____
CONDITION OF EQUIPMENT AFTER SERVICE CALL

8

SUMMARY

This manual was written to guide the clinical users of ultrasound toward the practices that insure continued peak performance of their equipment. The concept of quality assurance encompasses all procedures necessary to keep the equipment functioning properly. This includes knowledge of equipment operation, preventive maintenance procedures and acceptance and performance tests. These topics are covered in separate sections. A section on system performance and testing was added to inform and educate the clinical user concerning the pertinent equipment parameters that must be considered in a quality assurance program. Since many of these parameters can not be adequately tested at present, this section represents a guide for future developments in quality assurance research.

Quality assurance in a clinical subspecialty should exist on many different levels. Physicists or engineers can perform acceptance tests, the more technical routine performance tests and be available for consultations. The equipment service person can repair or replace faulty components, calibrate the equipment and perform the manufacturer's own quality assurance procedures. With the new equipment available the physician has more information present in the ultrasound image. Besides aiding in patient diagnoses, the increased information can aid the physician in diagnosing operator or equipment malfunction. The ultrasound technical specialist (technologist) can learn to better use and maintain the equipment as well as when to call in one of the available technical experts (physicist, engineer, or service person).

This manual is aimed at the clinical user. The recommended tests in Section 7 were selected to monitor the most important equipment parameters and to be simple to perform and interpret. More complicated tests are best left to the physicist or engineer. However, if the clinical user has some simple means of evaluating equipment performance then he has a greater feeling of control over the equipment and more common ground to communicate with the service person. Also, the individual who spends the most time with the equipment and who is primarily responsible for its proper use should be the most involved in its quality assurance program.

The recommended tests are based on the AIUM 100mm Test Object. When used properly (first check the liquid acoustic velocity) this simple to use test object will give excellent results. The clinical user should become experienced in its use and then rely on its test results as a prime indicator of equipment performance. In his experience with disputes over equipment performance, the author has **always** seen the AIUM 100mm Test Object properly indicate the level of equipment performance.

New quality assurance procedures are being developed in diagnostic ultrasound. In several years tissue equivalent test objects will become a standard in the clinical laboratory. Real-time and cardiac (M-mode) equipment will have also been added to the clinical quality assurance manual. New manuals on these topics are being developed (19). Diagnostic ultrasound is an exciting and rapidly growing imaging modality. Research in quality assurance procedures is endeavoring to keep pace with all technological advances so that the clinical user can maintain proper clinical use of his equipment.

9

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KB-Aero Tech
P.O. Box 350
Lewistown, PA 17044
(800) 233-7183
Ultrasound T ansducer Performance Parameters
Effects of Diagnostic Imaging
Volume 1 No. 1 Axial Resolution
Volume 1 No. 2 One-Quarter Wavelength Theory and Application
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6.2.2 Bandwidth Axial Resolution

The SUAR Test Object, also referred to as the ARTU Phantom, is available from Radiation Measurements, Inc., and Nuclear Associates (See 9.2 for details).

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REFERENCE SECTION

9.2 AIUM 100mm Test Object
Standard 100 Millimeter Test Object
Including standard procedures for its use.

Adopted as a standard at the 1974 AIUM Meeting, Seattle, Washington.

INTRODUCTION

The Standard 100 Millimeter Test Object consists of stainless steel rods mounted parallel to each other in a trapezoidal grid pattern. It is used for aligning, calibrating and measuring performance of ultrasonic pulse-echo diagnostic apparatus, including scanners.

1.0 SCOPE AND PURPOSE

1.1 The purpose of the standard is to define the Standard 100 mm Test Object and procedures for its use. The procedures are meant to be convenient for use by clinicians or technicians. It is suggested that some of the procedures (see Appendix I) be used daily or weekly to check instrument performance. With appropriate equipment described below, and some experience, this can be performed in a few minutes. Complete calibration should be done at least every six months.

1.2 The standard defines the geometrical arrangement and diameter of the rods comprising the Test Object. Details of construction are not part of the standard, although two designs are given in Appendix II, which is included for reference.

1.3 The Standard 100 mm Test Object is for use in performance tests of ultrasonic pulse-echo diagnostic apparatus in which the acoustic output pulse is heavily damped. Such a pulse is typically less than five cycles in duration. The Test Object is for use with A-mode, B-mode or M-mode apparatus designed for examination of the brain, heart, and abdominal regions and other regions of similar dimensions. It may be used with other acoustical systems that image targets of these dimensions.

1.4 When reporting or publishing results, the use of the Standard 100 mm Test Object for calibration should be mentioned or a B-scan should be shown. A complete characterization of the system must include other parameters; such as, acoustical intensity levels and exposure. These are beyond the scope of this standard.

1.5 The accuracy expected from the use of the Standard 100 mm Test Object will be approximately ± 0.5 mm with the transducer 10 to 50 mm from the top row of rods. This will require a liquid medium temperature stability and reproducibility of $\Delta T = \pm 3°C$.

1.6 The definitions and measurements of this standard apply to the apparatus as a whole including transducer, electronics, display and mechanical system. Similar information may be assembled through measurements of component parts. These measurements should be made in accordance with standard engineering practice and standards.[1-4] Such measurements are outside the scope of this standard.

2.0 DEFINITIONS

2.1 The acoustical and electrical ferminology of the American National Standards Institute[5] and the American Institute of Ultrasound in Medicine[6] shall be used wherever possible.

2.2 **Standard 100 mm Test Object**

The Standard 100 mm Test Object is defined by the schematic drawing of Fig. 1. It is a series of 0.75 mm (0.030 inch) diameter stainless steel rods arranged in a standard 100 mm x 100 mm square pattern with a 10 mm x 100 mm triangle across the top. The rod position tolerance is ± 0.25 mm (±0.010 inch). The Test Object is to be immersed in an air-free medium whose velocity of sound corresponds to that of the tissues being examined. If water is used, the temperature should be 47 ±3°C, which corresponds to the average velocity of sound in tissue of 1540 m/s (Fig. 2). Refer to Figs. 3 and 4 for sound velocities vs temperature in other suitable media. The top rods are to be about 10 to 50 mm below the scanning line of the transducer. (See Section 3 for procedures.)

The rod patterns were intended for the following uses:

2.2.1 One group of parallel rods (Row A in Fig. 1) in a vertical plane, to be scanned from the top side for depth calibration, measurement of gain as a function of

depth and measurement of vertical linearity. (This group also gives an indication of the acoustic beam shape with depth, since in scanned B-mode, the line target is generally displayed as a horizontal smear.)

2.2.2 One group of parallel rods (Row B in Fig. 1) in a horizontal plane at the bottom for scanned B-mode horizontal calibration and measurement of horizontal linearity.

NOTE A: In scanned B-mode both the vertical and horizontal grids should be imaged from a multiplicity of angles and positions to measure registration and linearity of the scanner and display.
NOTE B: If construction permits, the test object may be inverted for near position horizontal measurements with the parallel lines of Row B.

2.2.3 A group of rods (Row C, Fig. 1) in a vertical plane at decreasing spacings for measurement of beamwidth. These rods should be scanned linearly from the right side, or if construction permits, the test object should be turned +90 degrees so these rods are in a horizontal plane at the top.

2.2.4 A group of rods (Row D, Fig. 1) at 2,4,6 and 8 mm spacings from the horizontal line JK. These rods are for rapid measurement of the transducer dead-zone or "ring-down" distance.

2.2.5 A group of rods (Row E, Fig. 1) in a plane tilted 15 degrees from the centerline at 5,4,3,2, and 1 mm spacings for measuring axial or depth resolution. The top rod in this group is at the center of the 100 mm square pattern.
NOTE: These rods in this group are inclined 15 degrees from the centerline to decrease acoustical shadowing of the lower rods.

2.3 Standard Echo Display Level

2.3.1 A-Mode
The standard echo display level is an arbitrarily chosen pulse height on the oscilloscope display. It is for reference only, but should be the same throughout the tests and should be recorded. For example, a 4 cm pulse height on an 8 cm high display might be used.

2.3.2 B-Mode and M-Mode Including Gray Scale Displays
The standard echo display level is an intensity level equivalent to an arbitrary number of gray levels above the display zero level. The level should be consistent and recorded. For example, a 3 dB level above the display zero or threshold might be used, but in any case the system should be well below the saturation level. Any scanning motion should be specified, e.g., sector scan with an effective linear speed of n cm/sec of an M-mode time sweep of n cm/sec.

2.4 Resolution

2.4.1 A-Mode
Two targets are said to be resolved if the amplitude between the two echoes decreases below 0.7 of the maximum amplitude of the weaker echo which should be adjusted to Standard Echo Display Level. If the amplitude drops below 0.3 between the echoes, the targets are said to be completely resolved.

2.4.2 B-Mode or M-Mode
Two targets are said to be resolved if the display intensity between the two echoes decreases more than two 1.5 dB gray levels below the weaker of the echoes which should be set to the Standard Echo Display Level.

2.5 Dead Zone
The dead zone of an echoscope is defined as the distance corresponding to the time immediately after the transmitted pulse in which transducer reverberation and/or amplifier overloading causes or necessitates significantly reduced sensitivity, or otherwise seriously alters the echo patterns received.

3.0 PROCEDURE FOR USE OF STANDARD 100 mm TEST OBJECT

3.1 Requirements

3.1.1 A Standard 100 mm Test Object in a suitable water tank. Appendix I describes different methods of construction of this tank. Provision should be made for aligning the parallel rods normal to the scanner plane.

3.1.2 A suitable propagation medium with the velocity of sound adjusted to the tissue being examined.[7] Fig. 2 is a graph of sound velocity in water[8] and normal saline[9] vs temperature which may be used to determine the correct temperature.

NOTE: If adjustment of the velocity of sound in water or normal saline using temperature is inconvenient, the following methods may be used.

a. Variation in NaCl content. Fig. 3 is a graph of sound velocity vs NaCl concentration in water at 20°C.

NOTE: The stainless steel rods may be affected by this salt solution. If this method is chosen, the Test Object should be washed in tap water after use.

b. Variation in ethyl alcohol content.

Fig. 4 is a graph of sound velocity vs ethyl alcohol concentration in water at 20°C.[9]

c. Water that is to be kept for an extended period should have a suitable chemical added to prevent growth of microorganisms. The concentration of this added solution should not change the velocity of sound or acoustical impedance of the propagation medium more than one percent.

3.1.3 The Time-Varying Gain Control (TGC) is normally switched off or set to a minimum for these tests.

3.1.4 The echoscope and scanning apparatus under test, with nonspecified controls such as focus, brightness, etc., in known, repeatable positions typically used in practice. The transducer size, nominal (manufacturer's) working frequency and serial number should be recorded. The transducer is a major variable in these procedures. A completely new set of measurements should be made if the transducer is changed.

3.1.5 A correctly matched and calibrated attenuator, which is preferably included between the pulse generator and the transducer, but may be between the transducer and the receiver. (See Note 3 in Appendix I.)

3.2 Depth Calibration

Depth calibration is to be performed with the group of vertical rods on the left side of the Test Object. All rods should be displayed simultaneously. If scanning is required, the rods should be scanned linearly, (i.e., without rotation of the transducer) perpendicular to the plane of the rods.

a. Measure displayed distances y from recording with distance markers on or the graticule illuminated or directly from the display.

b. Plot y values as a function of true distance x which is 20 mm.

c. Fit a straight line to these points. This line can be described by the equation $y = ax + b$.

From this the following can be determined:

1. Error in zero calibration E_o = b(mm). (This parameter is important only for mechanically operated scanners.)
2. Percent error in sound velocity calibration $E_v = 100(1-a)$.
3. Maximum deviation from linearity δy(mm), where δy is the largest y distance from the straight line to any point (x,y).

d. A more rapid, but less precise check of calibration can be made by aligning the displayed echoes to the display markers or graticule.

3.3 Axial Resolution Measurement

Axial or depth resolution is measured with the inclined group of six rods in the center of the Test Object (Row E). The transducer axis shall be parallel to the plane of the centerline of the Test Object and normal to the top rod. In all modes, the transducer should be scanned linearly across this group of rods to measure resolution.

Axial resolution is the spacing of the two closest rods in the group which can be resolved. Echoscope sensitivity should be noted in accordance with the AIUM Standard.[10] This measurement should be repeated at several distances from the top rod (typically 50, 100 and 150 mm) and at several sensitivites for a complete characterization of the system.

3.4 Dead Zone Measurement

The dead-zone or "ring-down" distance is measured with the top group of rods. The transducer is adjusted to be 2 mm from the uppermost rod in the group. A linear scan is made parallel to plane FI. The distance from the transducer face to the first rod whose echo is resolved from the reverberation is the length of the dead zone. All rods further than this must also be resolved for this to be quoted as the dead zone measurement. If the 2 mm rod and all succeeding ones are resolved, the dead zone will be quoted as "less than 2 mm".

3.5 Lateral Resolution Measurement (Beam width)

Lateral resolution is measured with the group of rods at the right side of the Test Object. The Test Object may be turned +90 degrees for convenience putting these rods on the top side. A linear scan is made parallel to the plane of the rods H1. The rods will generally be displayed as lines rather than points. Lateral resolution is the spacing between the two closest rods which can be resolved. Echoscope sensitivity should be noted in accordance with the AIUM Standard.[10] This measurement should be repeated at several distances (typically 50, 100 and 150 mm) and at several sensitivities for a complete characterization of lateral resolution.

NOTE 1: When Test Object construction does not allow measurement of lateral resolution at several distances, the following method may be used.

Using rods in group A, the transducer is

to be oriented for maximum echo level from a rod at a chosen distance. The system attenuator is adjusted to obtain a standard echo display level. The attenuator is reduced 6 dB thereby increasing the display level. The transducer is moved to either side of the rod in a direction perpendicular to the plane FG and the rod. Lateral resolution is the total distance moved between the two transducer positions at which the standard echo display level is once again obtained. Note that the measurement may be slightly different from that obtained with rod group C.

NOTE 2: Both procedures apply to circular transducers, which may be focused or unfocused. For other shapes, the orientation of the transducer must be completely specified.

3.6 Time-Gain Characteristics

Time-gain (or equivalently, distance-gain) characteristics may be determined with the vertical rod group A. With the TGC switch off and the transducer acoustic axis fixed in the plane of the rods, the attenuator settings required to display each rod at the Standard Echo Display Level are recorded. The test is repeated with the TGC on at a known, repeatable position. The difference between the two attenuator settings for each rod as a function of distance is the time-gain characteristic.

NOTE: In equipment where one or more TGC parameters are variable, several tests should be made with the values of these parameters recorded.

3.7 Display Characteristics

3.7.1 A-Mode Linearity Measurement

An echo from an isolated rod of the test target is to be displayed at Standard Echo Display Level with the transducer fixed in place. The attenuation is then decreased in 3 dB steps (x), the display level (y) measured, and the results plotted as in Section 3.2. The maximum deviation from linearity $E_A = \delta y$, where δy is the largest y distance from the best fit straight line to any point (x,y).

3.7.2 B-Mode

Using an isolated single echo as above, the attenuator is adjusted to provide an echo intensity just below that which can be recorded photographically with brightness controls at normal operating position. The spot is recorded, the attenuation decreased by 1.5 dB, and the display position control changed to place the spot in new positions. This process is repeated to form a row of spots on the recording similar to an optical density step wedge and covering the entire gray scale. Where a two-level storage tube is used, the effect of increased signal on displayed spot-size is indicated.

3.8 Scanned B-Mode Alignment

The Standard Test Object is scanned at normal settings from at least three angles and several distances. Echoes from individual rods should superimpose subject to beamwidth characteristics at these distances. The area enclosed by various echoes from a given rod is then a measure of the smallest resolution element of the system.

The approximate dimensions of this area should be related to real dimensions of the Test Object and reported as a function of position.

The accuracy of area measurement can be checked by measuring the displayed area of the square formed by rods F through I.

Appendices to AIUM 100mm Test Object Standard

APPENDIX I

(This is not a part of the standard, but is included for reference)

Note 1.0 List of procedures to be performed daily (preferred) or weekly.

3.2.4 Depth calibration (tests electronic time base).

3.3 Axial resolution (tests transducer and electronics).

3.8 Scanned B-Mode Alignment (tests scanner registration).

Reference control settings must be determined and followed rigorously for meaningful results.

Note 2.0 Scan(s) for Publication of Results

A picture from a linear scan of the Test Object, 50 mm from, and parallel to plane FI is the minimum requirement for publishing results. Echoscope Sensitivity, nominal transducer frequency and diameter, and other relevant parameters should be given.

An additional picture of the Test Object made with three linear scans is required for complete display of results. The first scan is made with the transducer angled about 45 degrees to the left of vertical and the second angled similarly to the right of vertical. The third scan is made with the axis of the transducer vertical.

Note 3.0 The attenuator must be properly matched so that it does not alter the echo wave-shape. This may be checked by comparing the waveform of an echo from a rod without the attenuator in the line and then with the attenuator in place with zero attenuation. If these waveforms are comparable, put in 40 dB attenuation, increase receiver gain until the amplitude is the same as before, and check the waveform. It is recommended that a calibrated step attenuator be provided in the front panel of all echoscopes.

It may not be possible to isolate the pulse generator-transducer and transducer-receiver signal paths as when the pulse generator and receiver have only a common connector to the transducer. In this case a measurement within the accuracy required in this standard may be made using an attenuator in series with the transducer with 20 dB of attenuation, since the signal passes through the attenuator twice (once going out and once returning). All readings taken from the attenuator should then be multiplied by two (2.0). Attenuator matching in this case may be difficult.

APPENDIX II

CONSTRUCTION DETAILS

(This is not a part of the Standard, but is included for reference)

Fig. 5 is a schematic drawing of the "open" configuration[11] of the Test Object. This design requires an open water tank as shown in Fig. 6. Note that care must be taken in handling to avoid bending the rods. Also, the velocity of sound in the medium may change with evaporation if a solution is used to obtain the correct value. An additional thin plate (Fig. 5) may be used to support the transducer for dead-zone measurements if desired.

Fig. 7 is a schematic drawing of an "enclosed" configuration[12] of the Test Object. An ethyl alcohol, algae inhibitor and water solution maintaining the proper 1540 m/sec ultrasound velocity at room temperature may be sealed in the tank permanently. Thin acrylic plastic sheets, 1.45 to 1.6 mm (1/16") thick, on all five narrow sides of the tank, serve as windows through which pulsed ultrasound may pass with minimum distortion. These windows facilitate reproducible alignment of a transducer with the rods. Teflon tape covering the central 25 mm (1") of the windows allows trandsucers to slide freely along the windows. The tape and adhesive should be very thin, less than 0.1 mm (0.004") to avoid transmission problems. Air bubbles under the tape or in the tank must be eliminated. The sides and base of the tank may be constructed of 9.5 mm (3/8") thick acrylic or other transparent plastic and the stainless steel rods should be affixed at only one end to allow for thermal expansion and contraction of the liquid in the tank.

When using the enclosed tank, a minimum of coupling agent should be used between the transducer and window. The face of the transducer should be aligned to be parallel to the window for best results.

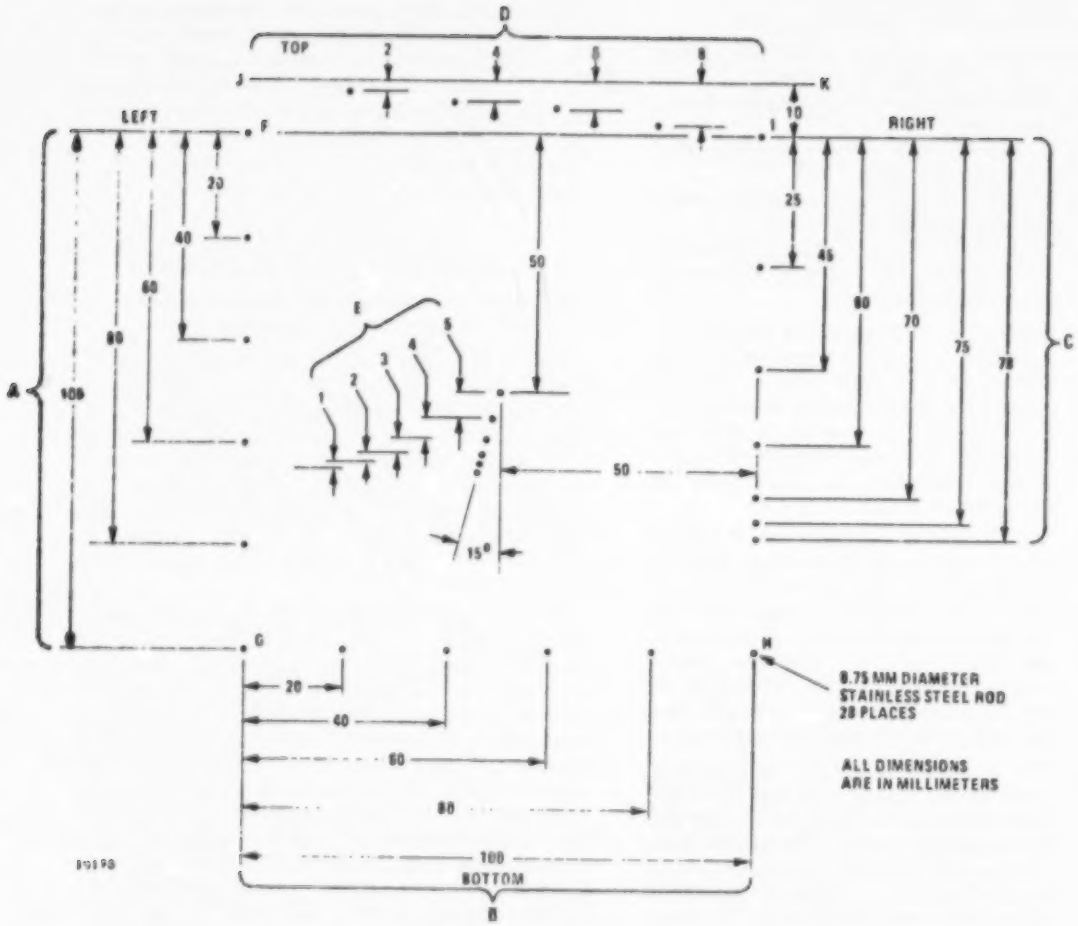

Figure 1. The Standard 100mm Test Object (0.75mm rods are normal to plane of the Figure.)

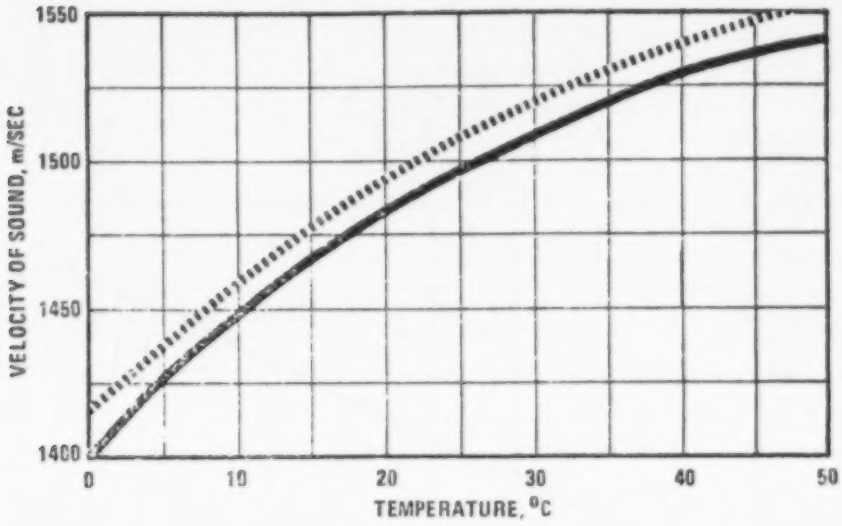

Figure 2. Velocity of Sound in Distilled Water vs Temperature (Reference 8) — solid line, and Normal Saline vs Temperature (Reference 9) — broken line.

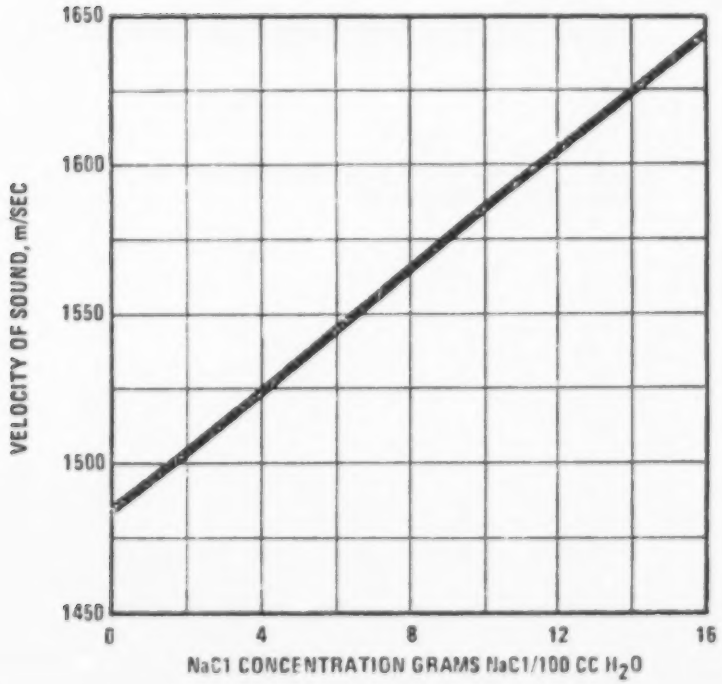

Figure 3. Velocity of Sound in NaCl/Water Solution at 20° C (Reference 9).

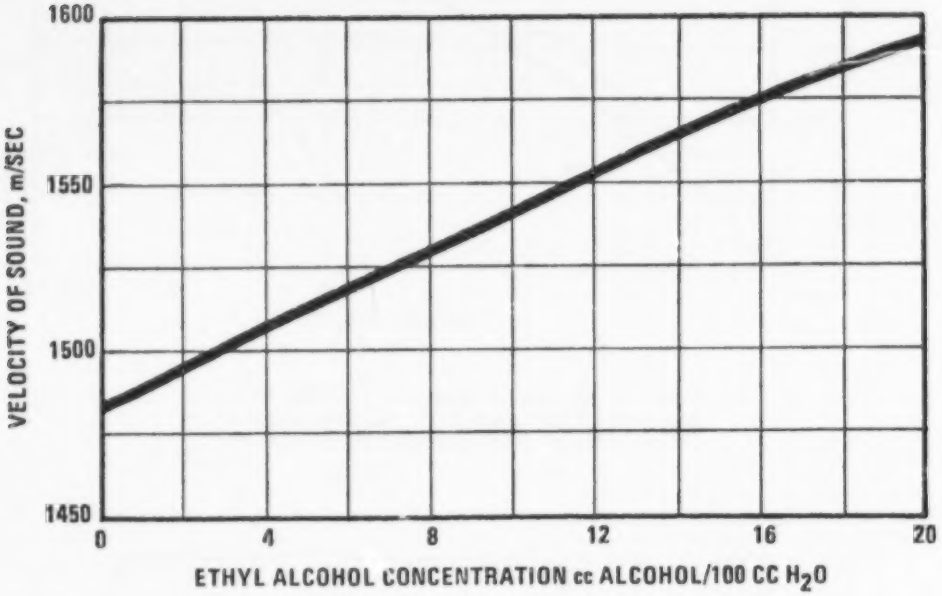

Figure 4. Velocity of Sound in Ethyl Alcohol/Water Solution at 20°C (Reference 9).

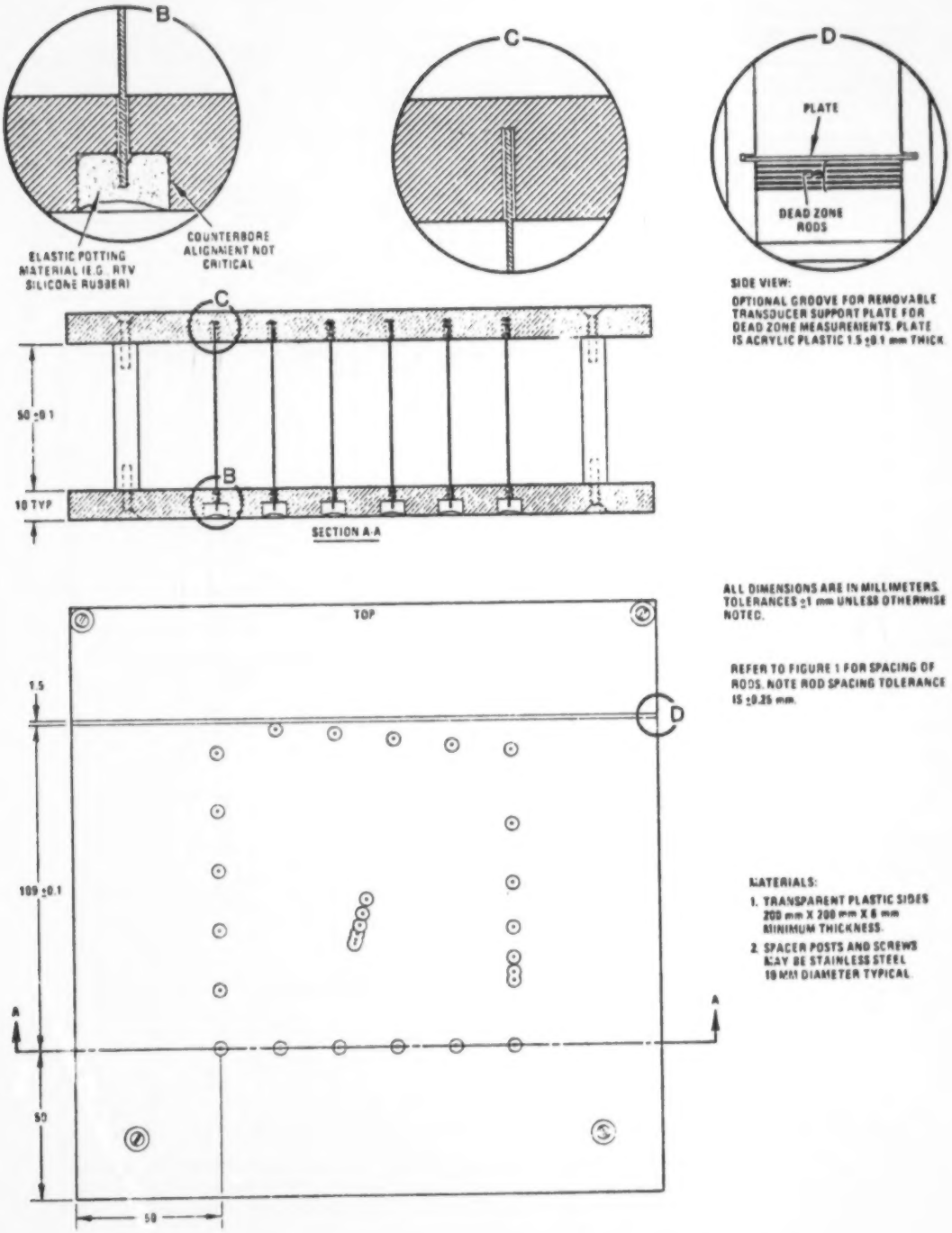
B
C
D
PLATE
DEAD ZONE RODS
ELASTIC POTTING MATERIAL (E.G. RTV SILICONE RUBBER)
COUNTERBORE ALIGNMENT NOT CRITICAL
SIDE VIEW:
OPTIONAL GROOVE FOR REMOVABLE TRANSDUCER SUPPORT PLATE FOR DEAD ZONE MEASUREMENTS. PLATE IS ACRYLIC PLASTIC 1.5 ±0.1 mm THICK
C
50 ±0.1
10 TYP
B
SECTION A-A
ALL DIMENSIONS ARE IN MILLIMETERS. TOLERANCES ±1 mm UNLESS OTHERWISE NOTED.
TOP
1.5
D
REFER TO FIGURE 1 FOR SPACING OF RODS. NOTE ROD SPACING TOLERANCE IS ±0.25 mm.
100 ±0.1
A
A
50
50
MATERIALS:
1. TRANSPARENT PLASTIC SIDES 200 mm X 200 mm X 6 mm MINIMUM THICKNESS.
2. SPACER POSTS AND SCREWS MAY BE STAINLESS STEEL 10 MM DIAMETER TYPICAL.

Figure 5. Typical "open" configuration of the Test Object.

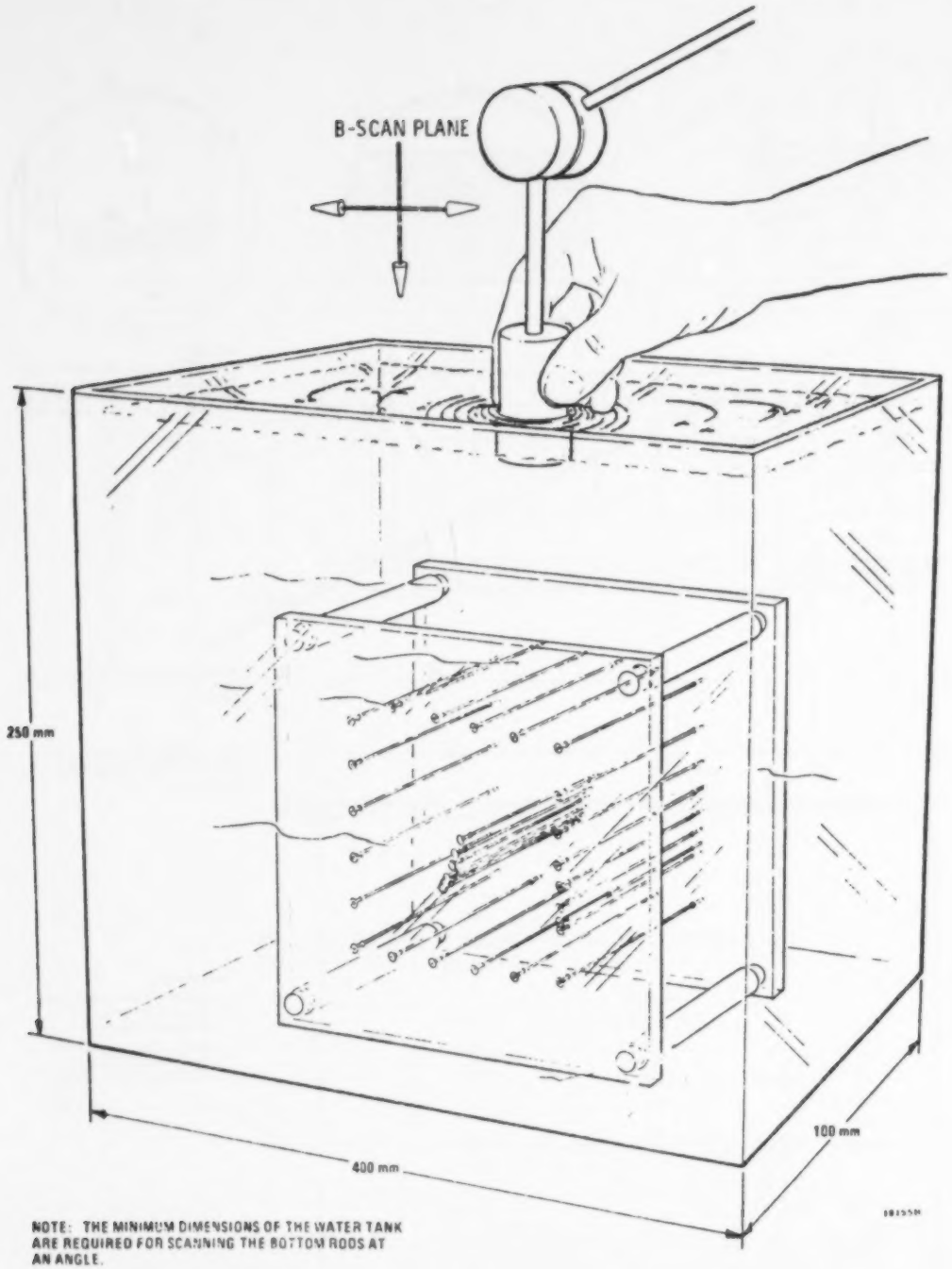
B-SCAN PLANE
250 mm
400 mm
100 mm
NOTE: THE MINIMUM DIMENSIONS OF THE WATER TANK ARE REQUIRED FOR SCANNING THE BOTTOM RODS AT AN ANGLE.

Figure 6. The 100mm Test Object (open configuration) in use.

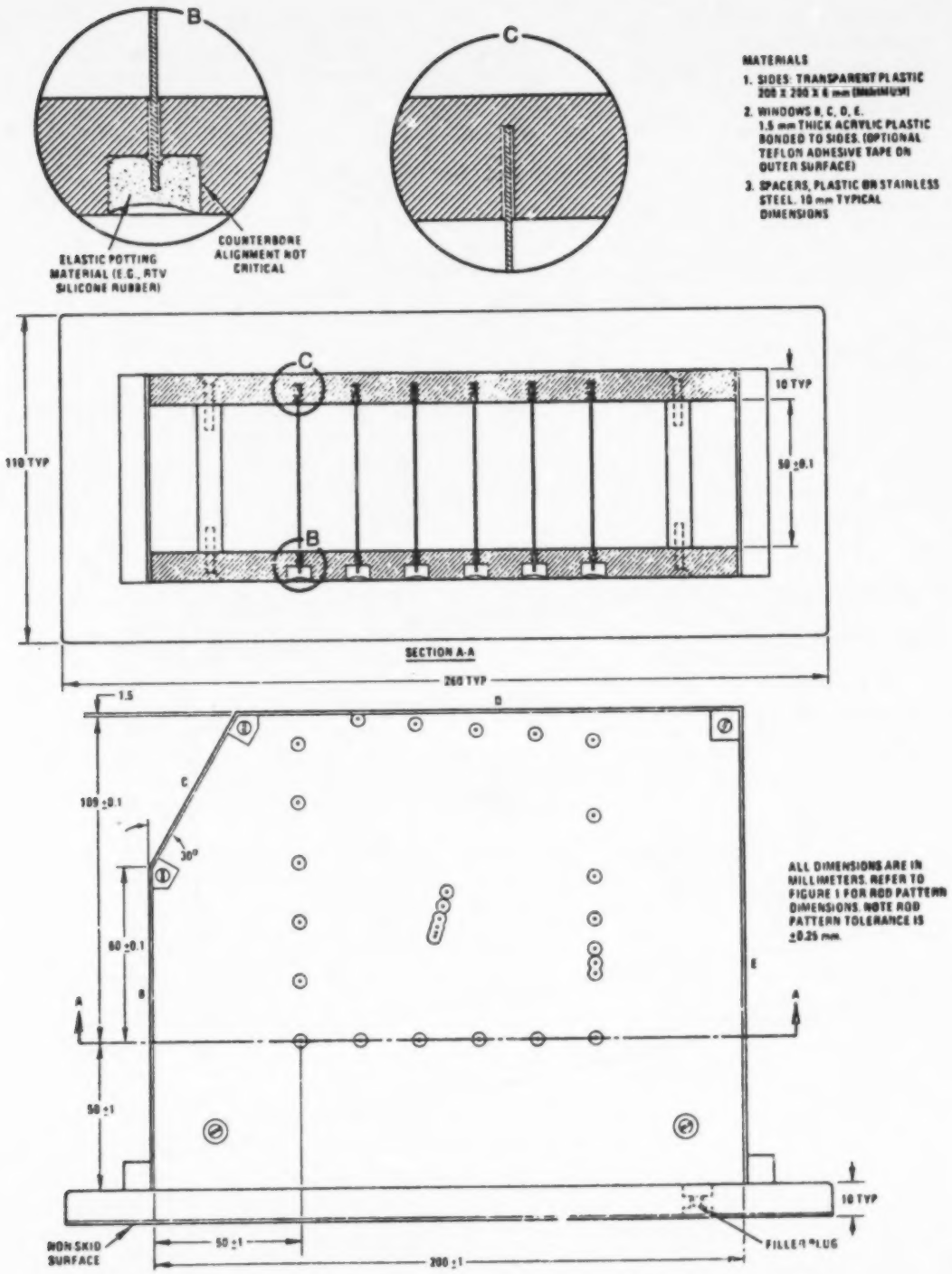
B
C
ELASTIC POTTING MATERIAL (E.G., RTV SILICONE RUBBER)
COUNTERBORE ALIGNMENT NOT CRITICAL
MATERIALS
1. SIDES: TRANSPARENT PLASTIC 200 X 200 X 6 mm
2. WINDOWS B, C, D, E. 1.5 mm THICK ACRYLIC PLASTIC BONDED TO SIDES. (OPTIONAL TEFLON ADHESIVE TAPE ON OUTER SURFACE)
3. SPACERS, PLASTIC OR STAINLESS STEEL. 10 mm TYPICAL DIMENSIONS
110 TYP
10 TYP
50 ±0.1
SECTION A-A
260 TYP
1.5
D
109 ±0.1
30°
60 ±0.1
50 ±1
ALL DIMENSIONS ARE IN MILLIMETERS. REFER TO FIGURE 1 FOR ROD PATTERN DIMENSIONS. NOTE ROD PATTERN TOLERANCE IS ±0.25 mm.
10 TYP
NON SKID SURFACE
50 ±1
200 ±1
FILLER PLUG

Figure 7. Typical "enclosed" configuration of the Test Object.

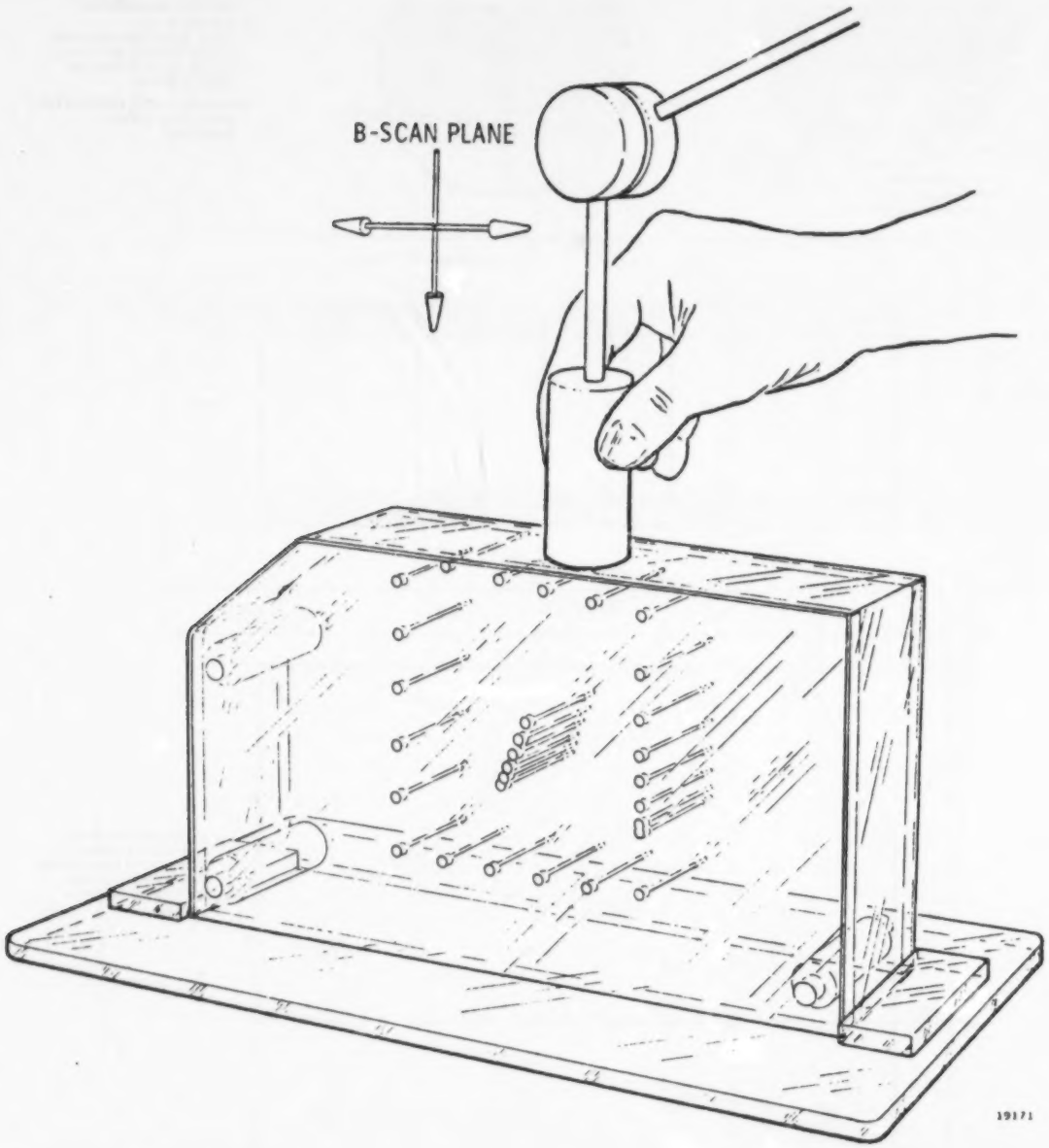

Figure 8. The "enclosed" Test Object in use.

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3350 Stuart Street
Denver, Colorado 80212
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(916) 451-4259

Modern Electronic Diagnostics Corp.
820 West Hyde Park Blvd.
Inglewood, California 90302
(213) 673-2201

Ross Chemical Assoc.
4237 Baldwin
El Monte, California 91731
(213) 579-5880

Mr. Hy Glasser
Nuclear Associates, Inc.
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Carle Place, New York 11514

REFERENCE SECTION

9.3 Commercial Suppliers of Ultrasound Test Objects

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Series 104
Cyst Phantom Organ equivalent material
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included cyst 13 mm dia. x 45 mm length

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Enclosed object

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FDA 80-8034 Report of State and Local Radiological Health Programs, Fiscal Year 1978 (PB 80-130867, $6.00).

FDA 80-8035 Regulations for the Administration and Enforcement of The Radiation Control for Health and Safety Act of 1968 (July 1980) (GPO 017-015-00173-3, $3.75) (supersedes FDA 79-8035).

FDA 80-8057 Nationwide Evaluation of X-Ray Trends: Dental X-Ray Data (brochure) (supersedes FDA 78-8057).

FDA 80-8070 Bureau of Radiological Health Publications Subject Index (supersedes FDA 80-8070, October 1979).

FDA 80-8092 Biological Bases for and Other Aspects of a Performance Standard for Laser Products (PB 80-128648, $6.00).

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FDA 80-8124 Optimization of Chest Radiography - Proceedings of a Symposium Held in Madison, Wisconsin, April 30-May 2, 1979 (GPO 017-015-00176-8, $7.50).

FDA 80-8125 Research Into the Biological Effects of Ionizing Radiation in The Bureau of Radiological Health (GPO 017-015-00172-5, $4.00).

FDA 80-8126 Symposium on Biological Effects, Imaging Techniques, and Dosimetry of Ionizing Radiations (July 1980) (GPO 017-015-00175-0, $8.00).

FDA 80-8127 Guide for the Filing of Annual Reports (21 CFR Subchapter J, Section 1002.11).

FDA 80-8128 The Selection of Patients for X-ray Examinations: The Pelvimetry Examination (GPO 017-015-00174-1, $2.00).

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FDA 80-8131 Vignettes of Early Radiation Workers: A Videotape Series (flyer).

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